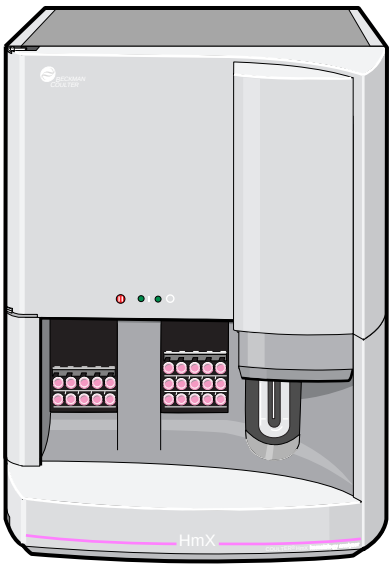
COULTER® HmX Hematology Analyzer with Autoloader

Operator's Guide



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COULTER CORPORATION
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LEGAL NOTICES

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Might cause injury.
CAUTION - Might cause damage to the instrument.
IMPORTANT - Might cause misleading results.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

Beckman Coulter, Inc. urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but it is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

WARNING Risk of operator injury if all covers are not secured in place prior to instrument operation or you attempt to replace a part without carefully reading the replacement instructions. Do not attempt to replace any component until you carefully read the instructions for replacing the component.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

REVISION STATUS

Initial Issue, 6/99
Software version 1.0.

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

REVISION STATUS

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CONTENTS

This introductory section contains the following topics:

- How to use your COULTER HmX Hematology Analyzer with Autoloader Documentation set
- About this Manual
- Conventions
- Hot Keys

HOW TO USE YOUR COULTER® HmX HEMATOLOGY ANALYZER WITH AUTOLOADER DOCUMENTATION SET

Use the **Reference** manual for in-depth information about what the instrument does, the methods it uses, its specifications, and information on installation, safety and software options.

Use the **Special Procedures and Troubleshooting** Manual to run a calibration, perform reproducibility and carryover checks, and to clean, replace or adjust a component of the instrument. The troubleshooting tables appear at the back of the manual.

Use the **Operator's Guide** for the day-to-day running of your instrument. Read the System Overview chapter to become familiar with the different parts of your system. Then go through the detailed step-by-step procedures of start up, running controls and samples, reviewing data and shutdown.

Use the **Host Specifications** Manual to locate information about transmission to a host computer.

Use the **Master Index** to locate a subject in your documentation set.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine quickly which manual contains the information you need.

ABOUT THIS MANUAL

Your HmX Hematology Analyzer with Autoloader Operator's Guide provides step-by-step instructions for the day-to-day running of your instrument.

This information is organized as follows:

- Chapter 1, System Overview
  Identifies and defines the function of the system components of the HmX Hematology Analyzer with Autoloader. Gives an overview of the software menu structure and the DMS status line.
- Chapter 2, Startup and Controls
  Contains step-by step instructions for performing daily start up and quality control procedures. Includes information on control run, review or report, graphs, $\overline{X}_B$ analysis, differential comparison, and mode to mode.
- Chapter 3, Sample Analysis
  Contains step-by-step instructions for performing sample analysis in the Primary, Secondary, Predilute, and Retic modes. Information about using the Worklist and Host Worklist is also included.

- Chapter 4, Data Review
  Contains information about reviewing the data on the Run Samples screen such as histograms, scatterplots, parameter codes, flags, and messages. Also presents information on Data Base Query and Workload Recording.
- Chapter 5, Shut Down
  Contains step-by-step instructions for shutting down your system for short or prolonged periods.
- Chapter 6, Set Up
  Contains information on how to set up control files, sample analysis options, and system options.

CONVENTIONS

This manual uses the following conventions:

- *ITALICS* indicate screen messages such as *RESET THE SYSTEM* or *Press any key.*
- **Bold** indicates
  - a menu item such as **Run Samples**.
  - a function such as **F3 Run**.
- The software path to access the needed function or screen appears in a series separated by double arrow heads. For example, the path to the Reagents set up screen is:

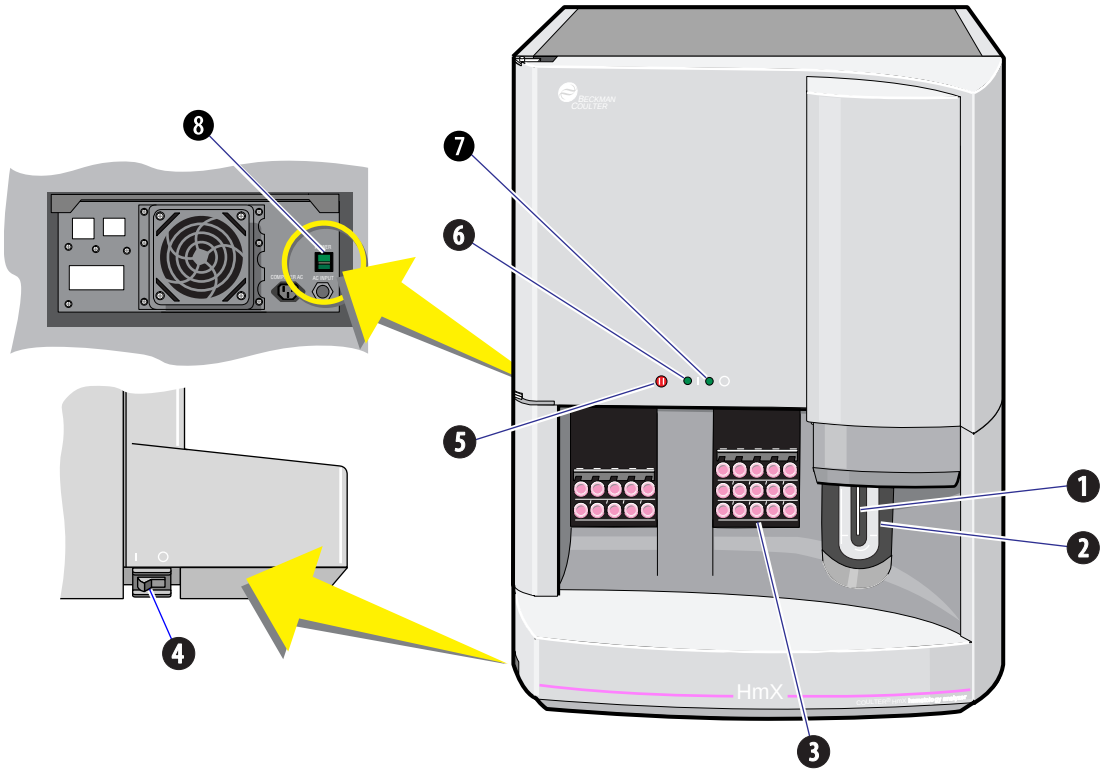
  Special Functions ▸▸ Set Up ▸▸ System Set Up ▸▸ Reagents.

  To select a menu item, highlight it then press Enter or press the alphabetic key on the keyboard that corresponds to the letter displayed in black within the name of the menu item.
- ▢ indicates a key (such as Enter).
- ▢ ▢ indicates to press and release the first key listed, then press and release the next key listed.
- ▢+▢ indicates to press and hold the first key listed, then press the next key.

HOT KEYS (SHORTCUTS)

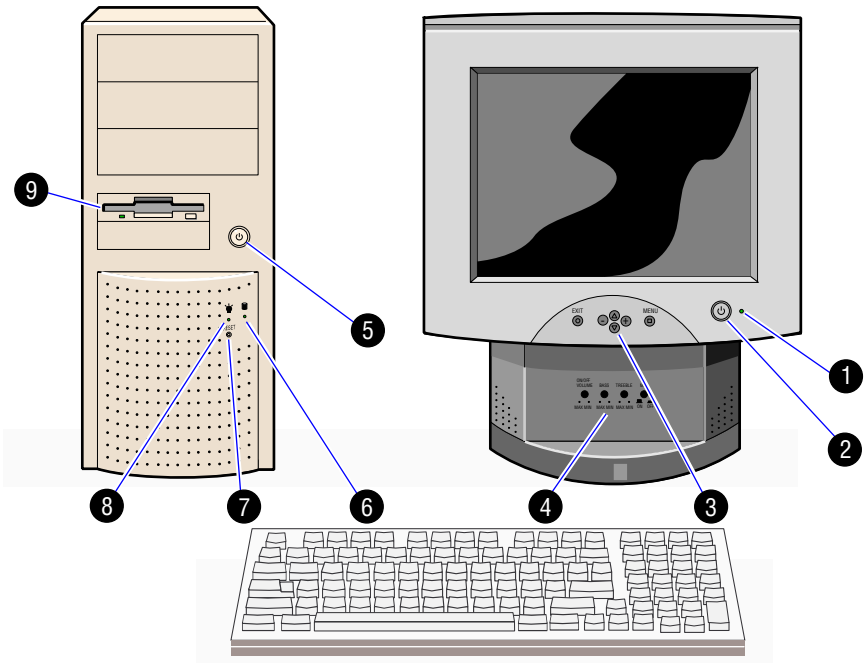
F1	Go to the Access screen. This is only available when the Main Menu is displayed.	Alt+End	Stops instrument beeping and removes the error message at the bottom of the screen.
F4	Print.	Ctrl+F2	Move from the current screen to the Error file and back to the original screen.
F9	Exit (unless the **F3 Run** window is displayed, then the function of F9 is Stop.)	Ctrl+W	Move from the Sample Analysis screen to the Worklist and back when a sub-menu or window is not displayed.
F10	Save and/or return to the previous screen.	Ctrl+F9	Stop cycle.

1.1 HmX WITH AUTOLOADER MAIN UNIT COMPONENTS



1. Aspirator probe. Use this to aspirate from open vials, predilute specimens, and retic preparations.
2. Sample bar. Press this to start aspiration from an open vial, predilute specimen, or retic preparation.
3. Loading bay. Load cassettes here.
4. Standby/Reset rocker switch. Use this switch to put the instrument in the standby state or to reset the system (refer to Special Procedures and Troubleshooting manual for reset procedure). The **I** symbol indicates the ready position and the **O** symbol indicates the standby position.
5. Emergency Stop button. Use this button to immediately stop the autoloader mechanism.
6. Ready indicator light. Main power is on and the Standby/Reset rocker switch is in the ready position. Instrument is ready to operate.
7. Standby indicator light. Main power is on and the Standby/Reset rocker switch is in the standby position. Voltages are applied to a memory location in the analyzer but everything else is powered down. To return to the ready state, put the Standby/Reset rocker switch in the ready position, **I**.
8. Main power On/Off rocker switch. This is located on the back of the instrument.

1.2 COMPUTER, MONITOR AND KEYBOARD



Note: The design of your computer and monitor may differ from this illustration. If so, refer to the manufacturer's documentation for information on controls and indicators.

1. Monitor power indicator light. Glows when power is on.
2. Monitor power On/Off switch.
3. Monitor menu controls. Not used routinely.
4. Monitor audio controls. Not used with the HmX Hematology Analyzer.
5. Computer power On/Off switch.
6. Hard disk indicator light. Glows when the computer is saving or retrieving data
7. Computer reset button. Used only in special circumstances. If you reset the computer, you must also reset the system using the Standby/Reset switch on the main unit before you return to normal operation.
8. Computer power indicator light. Glows when power is on.
9. Diskette drive. Used to upload COULTER 5C cell control file data and archive patient sample results. Indicator light glows when saving or retrieving data.

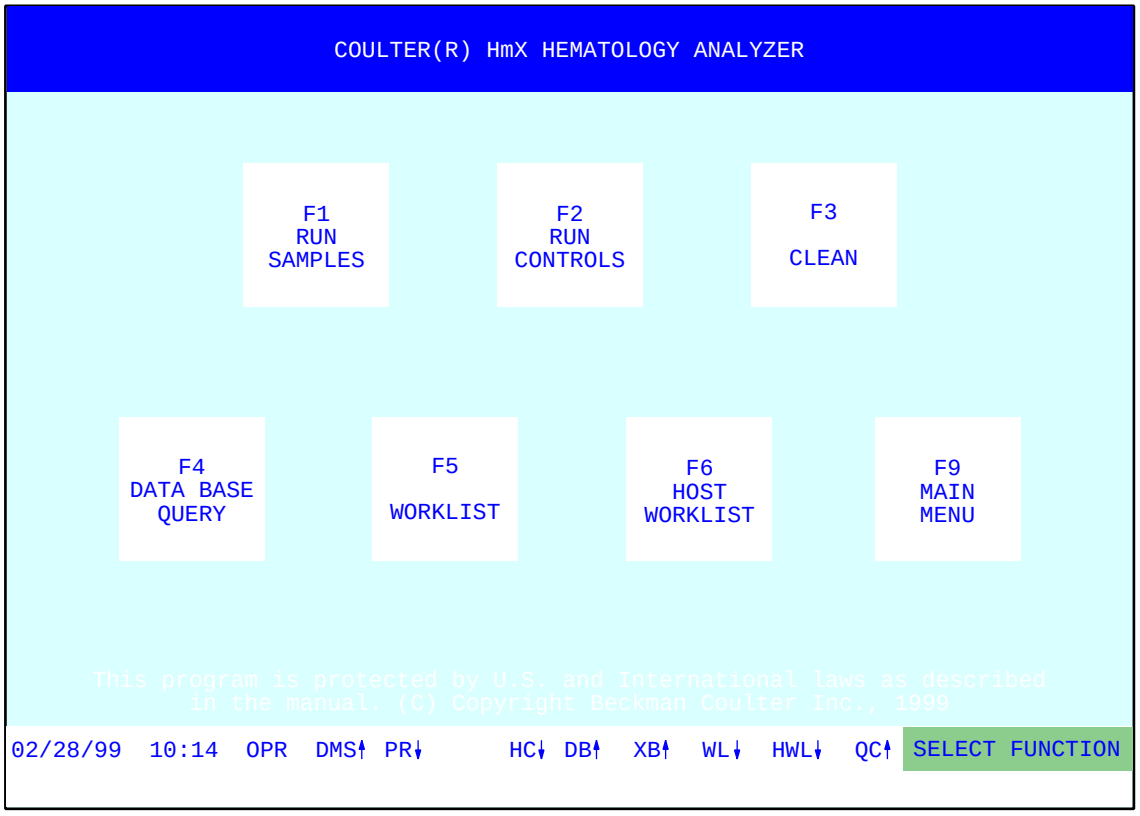
Spacebar. Toggles options. Press the spacebar to continue when the monitor screen is blank.

Cursor keys move the cursor to highlight menu items, scroll up and down screens, or move to a field on a screen to enter or edit data.

All other keys. Function is defined on each screen and in individual procedures.

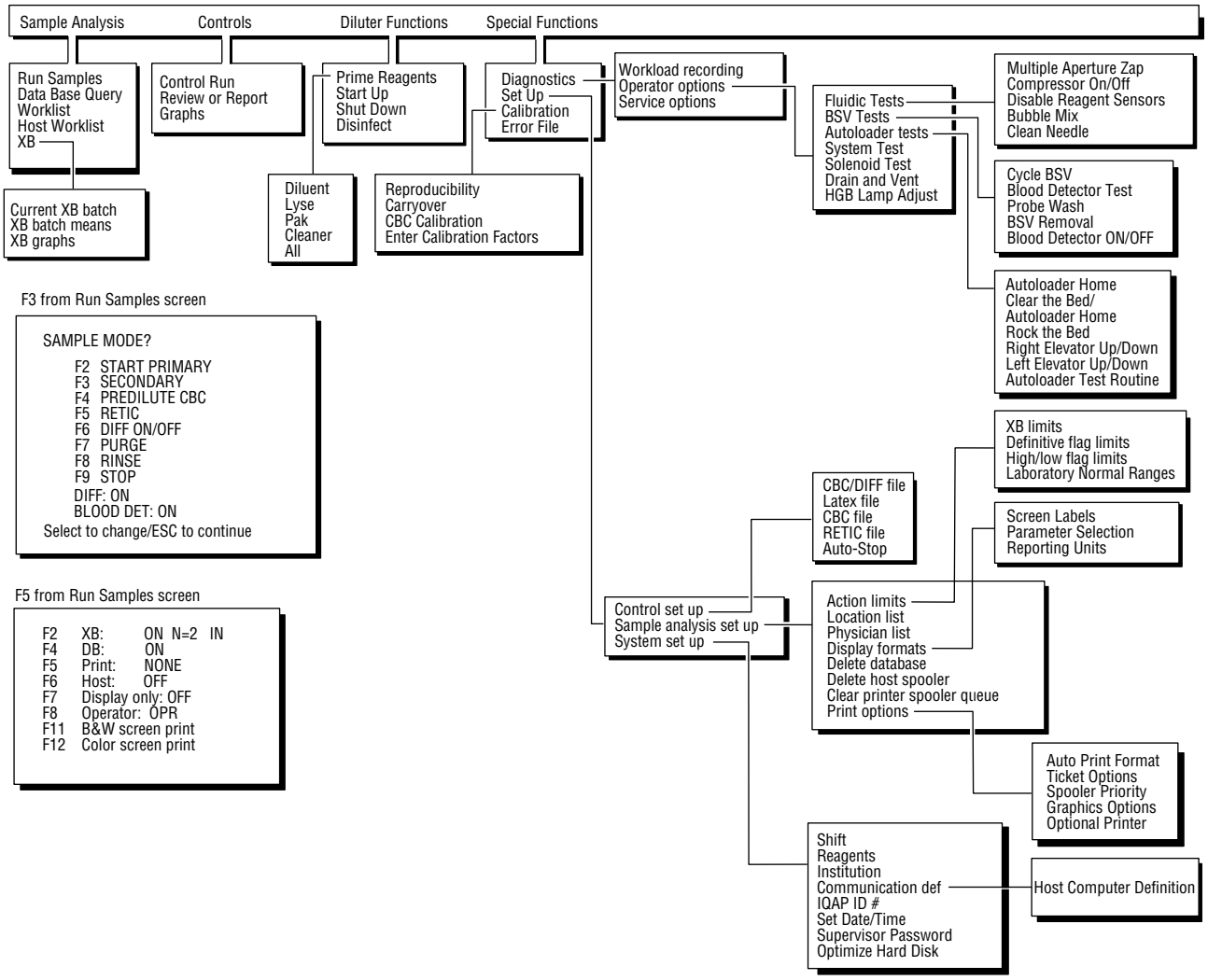
1.3 ACCESS SCREEN

The Access screen provides you with quick access to the most commonly used areas of the software. It is the first screen to appear after a system reset or power up. If you go to any of these areas using the Access screen, you will automatically return to the Access screen upon exit. The Access screen is also available from the Main Menu by using the F1 key.



1.4 SOFTWARE MENU TREE

The Main Menu consists of the four items listed across the top of the menu tree: **Sample Analysis**, **Controls**, **Diluter Functions**, and **Special Functions**.



1.5 RUN SAMPLES SCREEN OPTIONS

F5 Optns:

```
F2   XB:     ON N=2 IN
F4   DB:     ON
F5   Print:  NONE
F6   Host:   OFF
F7   Display only: OFF
F8   Operator: OPR
F11  B&W screen print
F12  Color screen print
```

Table 1.1 F5 from Run Samples Screen

F2 XB: ON N=2 IN	Turns XB ON and OFF. N is the number of samples stored in the current batch. Also displays the status of the last completed batch (IN or OUT).
F4 DB: ON	Turns the data base ON and OFF. Default setting is ON.
F5 Print: NONE	Sets the automatic printing of samples to the graphic printer. Choose between NONE, NORMALS, ABNORMALS or ALL. Default setting is NONE.
F6 Host: OFF	Turns the automatic host transmission ON and OFF. Default setting is OFF.
F7 Display only: OFF	If ON, then XB, DB and HOST turn OFF. Default setting is OFF.
F8 Operator: OPR	Enter up to three alphanumeric characters for an Operator ID. Default setting is OPR.
F11 B&W screen print	Initiates a large black and white screen print of the current sample.
F12 Color screen print	Initiates a large color screen print of the current sample if your printer can print in color.

Note: After a system reset, these options return to their default settings. Be sure to set them up again according to your laboratory's protocol before running patient samples.

Note: Print, Host and Operator can also be set up from the Main Menu using **F5-Options**.

1.6 STATUS LINE

The status line at the bottom of your screen indicates the current operating status of the HmX Hematology Analyzer with Autoloader.

Table 1.2 Status Line Definition

Symbol	Refers to	↑	↓	Red	Yellow	White
DMS	Data Management System	Connected to Analyzer.	Not connected to Analyzer.	Not communicating with Analyzer.	DMS busy or receiving data.	DMS is OK.
PR*	Graphics Printer	Autoprint is set to ALL, ABNORMALS, or NORMALS.	Autoprint is set to NONE.	Printer is off-line, or printer is out of paper.	Printer is printing.	Printer and DMS are connected.
HC	Host Computer	Auto transmission ON.	Auto transmission OFF.	Not connected to host.	Sending data to host computer.	Host and DMS are connected.
DB	Data Base	Store is ON.	Store is OFF.	Data Base is not functional. System stops. Reset the system and rerun last 2 samples.	Data Base is storing data.	Data Base is OK.
XB	$\overline{X}_B$ Analysis	XB is ON.	XB is OFF.	Last completed batch was OUT.	N/A	Last completed batch was IN.
WL	Worklist	Preassigned entries pending on Worklist.	No preassigned entries on Worklist.	3 consecutive or 10 total error messages are in the status field.	The Worklist is full. (300 preassigned samples)	Worklist is OK.
HWL	Host Worklist	Preassigned entries pending on the Host Worklist.	No preassigned entries on Host Worklist.	Host Worklist is full.	DMS is receiving preassigned samples from the host computer.	Host Worklist is OK.
QC	Quality Control	Auto-Stop is ON.	Auto-Stop is OFF.	Last control run had an error message.	Receiving a control run.	Results of last control run are OK.
P2	Additional Graphics Printer.	Autoprint is ON.	Autoprint is OFF.	Printer is off-line OR printer is out of paper.	Printer is printing.	Printer and DMS are connected.

*Changes to MA for manual printing, BA for batch printing and AU for auto-printing.

IMPORTANT Operating the HmX Hematology Analyzer with Autoloader with open doors or panels introduces electrical interference which can cause misleading results. Operate the HmX Hematology Analyzer with Autoloader with all doors and panels closed.

2.1 STARTUP

1. Are Start Up results already displayed as the result of a Clean cycle?
   - If no, go to step 2.
   - If yes, go to step 3.

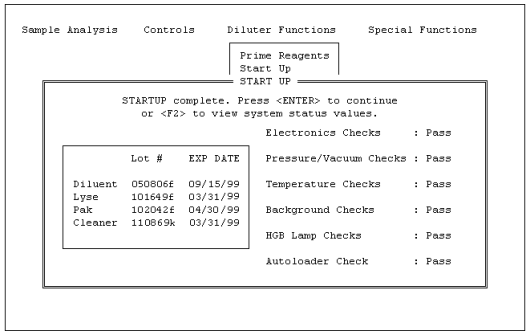
   Note: The Clean cycle consists of 30 minutes in Shut Down followed by an automatic Start Up. See Chapter 5, Shut Down for more information.

2. To begin Start Up
   a. Select **Diluter Functions ▸▸ Start Up**.
   b. Press Enter.

3. Once Start Up is complete, evaluate the display. Expired reagents and failed checks appear in red.

   If the Autoloader Check fails, place a cassette in the loading bay then select **Special Functions ▸▸ Diagnostics ▸▸ Operator Options ▸▸ Autoloader Tests ▸▸ Autoloader Test Routine.** If there are any errors generated during the test, refer to the Special Procedures and Troubleshooting manual to continue troubleshooting.

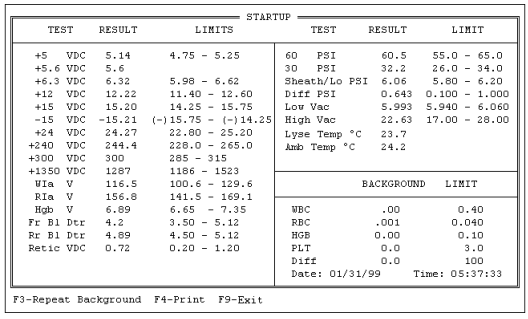
   Note: Results print automatically. For additional printouts, press F4.



4. Press F2 to view detailed results.

   Make sure the Background and other Start Up results are within limits.

   Results outside limits turn red.
   - If a background count is red, press F3 **Repeat Background**.
   - See the Special Procedures and Troubleshooting Manual for additional troubleshooting.



2.2 CONTROL RUN

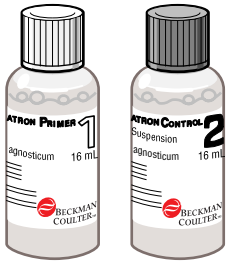
Preparation

Ensure that a control file is set up for each control you intend to run. If you need to set up a control file, refer to Heading 6.2, Control Set Up.

LATEX

Analyze COULTER LATRON™ primer and control once each day.

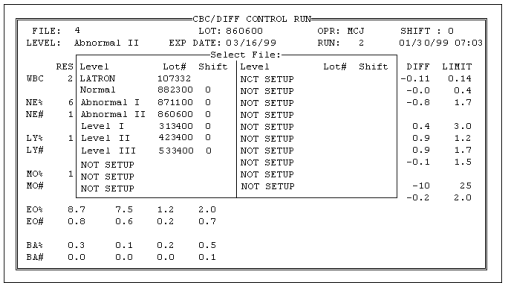
1. Make sure the LATRON primer and control are within the correct temperature range. See the package insert.



2. Access the Latex Control Run screen:
   - at the Access screen, press F2 **RUN CONTROLS**

     OR
   - at the Main Menu, select **Controls** ▸▸ **Control Run**.

3. If the LATRON file does not appear
   a. Press F2 **File**.
   b. Move the cursor to highlight the LATRON file.
   c. Press Enter.



4. Press F3 **Run** F4 **PRIMER**.

```
SAMPLE MODE?

    F3  CONTROL (SECONDARY)
    F4  PRIMER
    F7  PURGE
    F8  RINSE
    F9  STOP


Select to change/ESC to continue
```

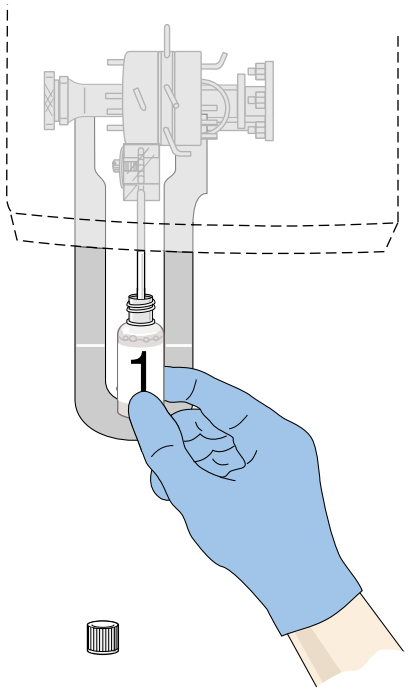
5. Cycle the primer (bottle 1):

IMPORTANT Removing the primer bottle before you hear the beep can cause falsely increased primer results. Do not remove the primer bottle until you hear the beep.

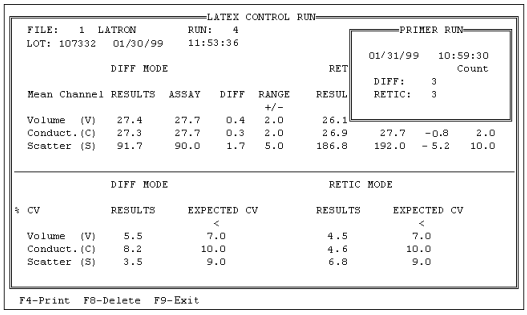
a. Immerse the aspirator tip completely in the primer.

b. Press and release the sample bar.

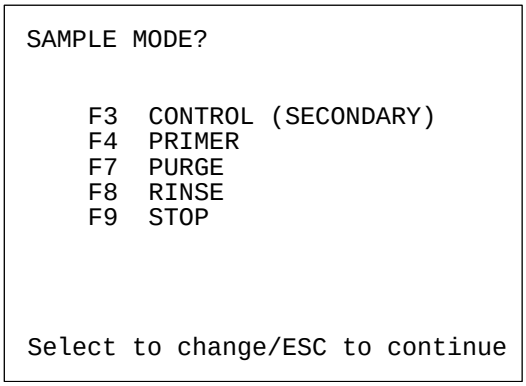
c. Remove the primer bottle when you hear the beep.



6. Evaluate primer results:
   a. Are both counts ≤ 500?
      - If yes, go to step 7.
      - If no, go to step 6b.
   b. Cycle a new vial. Make sure it is free of bubbles. Are both counts ≤ 500?
      - If yes, go to step 7.
      - If no, press F4 to print the screen then call your Beckman Coulter representative.


LATEX CONTROL RUN
FILE: 1 LATRON
LOT: 107332 01/30/99
RUN: 4
11:53:36
PRIMER RUN
01/31/99 10:59:30
Count
DIFF: 3
RETIC: 3
DIFF MODE
RET
Mean Channel RESULTS ASSAY DIFF RANGE +/- RESUL
Volume (V) 27.4 27.7 0.4 2.0 26.1
Conduct.(C) 27.3 27.7 0.3 2.0 26.9 27.7 -0.8 2.0
Scatter (S) 91.7 90.0 1.7 5.0 186.8 192.0 - 5.2 10.0
DIFF MODE
RETIC MODE
% CV RESULTS EXPECTED CV < RESULTS EXPECTED CV <
Volume (V) 5.5 7.0 4.5 7.0
Conduct.(C) 8.2 10.0 4.6 10.0
Scatter (S) 3.5 9.0 6.8 9.0
F4-Print F8-Delete F9-Exit

7. Press Esc to remove the Primer Run window.
8. When *SELECT FUNCTION* appears on the status line, press F3 **Run** F3 **CONTROL (SECONDARY)**.



9. Gently mix the control. Invert the bottle 5 to 8 times.

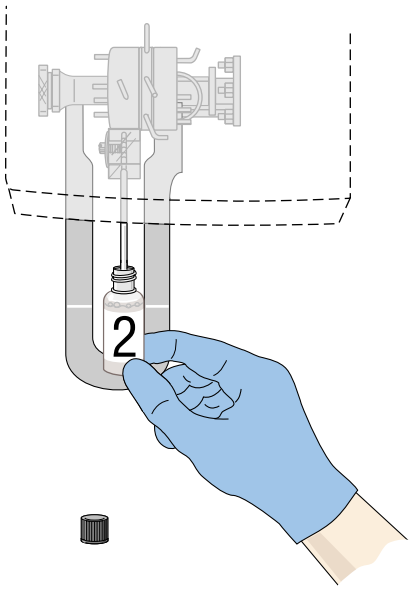
10. Cycle the control (bottle 2):

IMPORTANT Removing the control bottle before you hear the beep can cause misleading control results. Do not remove the control bottle until you hear the beep.

a. Immerse the aspirator tip completely in the control.

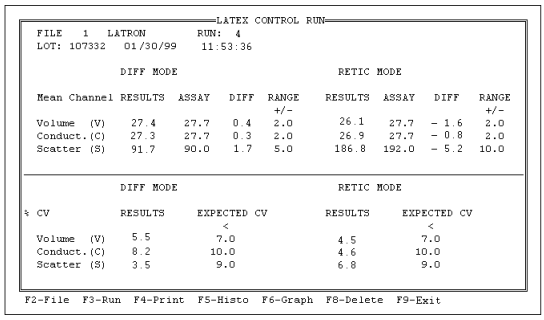
b. Press and release the sample bar.

c. Remove the control bottle when you hear the beep.



11. Check for H (High) or L (Low) beside the results for both modes.
    - If there are no H's or L's, results are within range.
    - If you see an H or L, go to Table 2.1. Follow the troubleshooting steps until you solve the problem.

12. Optional: Press F4 to print the results for your logbook.



LATEX CONTROL RUN

FILE 1 LATRON RUN: 4
LOT: 107332 01/30/99 11:53:36

Mean Channel	DIFF MODE RESULTS	ASSAY	DIFF	RANGE +/-	RETIC MODE RESULTS	ASSAY	DIFF	RANGE +/-
Volume (V)	27.4	27.7	0.4	2.0	26.1	27.7	- 1.6	2.0
Conduct.(C)	27.3	27.7	0.3	2.0	26.9	27.7	- 0.8	2.0
Scatter (S)	91.7	90.0	1.7	5.0	186.8	192.0	- 5.2	10.0

% CV	DIFF MODE RESULTS	EXPECTED CV <	RETIC MODE RESULTS	EXPECTED CV <
Volume (V)	5.5	7.0	4.5	7.0
Conduct.(C)	8.2	10.0	4.6	10.0
Scatter (S)	3.5	9.0	6.8	9.0

F2-File F3-Run F4-Print F5-Histo F6-Graph F8-Delete F9-Exit

Table 2.1 When LATRON™ Control is Out of Limits

Possibility	Action
Assigned value or range is incorrect.	Be sure the assigned values and ranges match the ones on the LATRON control package insert. If in error, correct them by selecting **Special Functions ▸▸ Set Up ▸▸ Control Set Up.**
Bubbles in the flow cell or improper vial handling	Rerun the primer and then the control.
Control is: • contaminated • improperly mixed • past open-vial expiration date	Ensure that the aspirator tip is clean and dry. Try a new vial of LATRON control. Mix gently according to directions on the package insert. Do not use expired control.
Plugged flow cell.	1. Press [F3] **Run**. 2. Press [F7] **PURGE** to purge the flow cell. 3. Press [F4] **PRIMER**. Cycle the LATRON primer again. 4. Press [Esc] . 5. Press [F3] **Run** [F3] **CONTROL (SECONDARY).** Cycle the LATRON control again. 6. If the control is still "out," repeat steps 1 through 5. 7. If the problem remains, either: • Perform Shutdown or • Turn the DIFF OFF and run CBCs only then call your Beckman Coulter representative for help.
There is an instrument change.	Call your Beckman Coulter Representative for help.

Cycling COULTER 5C® Cell Controls in Primary Mode with Bar-Code Labels

Your HmX Hematology Analyzer with Autoloader is a totally automated, multitasking system. COULTER 5C cell control, with bar-code labels, is the recommended method of QC. The instrument recognizes a control by its bar code and automatically assigns the control results to the correct file. If the bar-code label cannot be read, follow the procedure Cycling Commercial Cell Controls without Bar-Code Labels.

IMPORTANT If you cycle 5C cell control with the DIFF OFF, differential results do not post to the control file and therefore are not evaluated for being IN or OUT of control. Cycle 5C cell control with the DIFF ON.

IMPORTANT Misleading results can occur if 5C cell control is not prepared properly. Follow the procedure on the package insert to properly warm and mix 5C cell control.

1. Follow the directions on the cell control package insert for storage, preparation and mixing.
2. Does *SELECT FUNCTION* appear at the lower right corner of the DMS screen?
   - If no, go to step 3.
   - If yes, continue with this step.

   a. Access the Run Samples screen:
      - at the Access screen, press F1 **RUN SAMPLES**

        OR
      - at the Main Menu, select **Sample Analysis ▸▸ Run Samples**.

   b. The instrument automatically prepares itself for Primary mode, DIFF ON. Go to step 7.
3. Access the Run Samples screen:
   - at the Access screen, press F1 **RUN SAMPLES**

     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Run Samples**.
4. Press F3 **Run**.

5. Make sure the DIFF is ON. If it is OFF, press F6 **DIFF ON/OFF**.

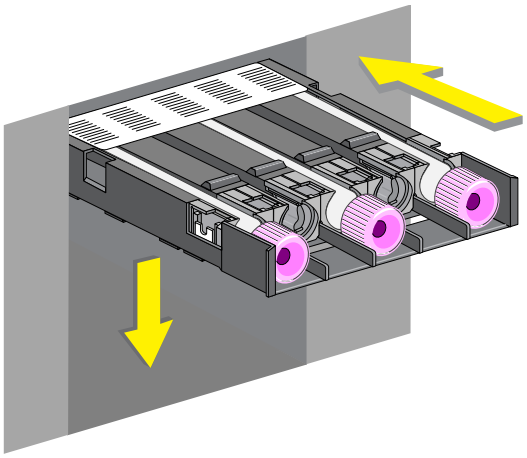
   Note: If **SAMPLE MODE?** is not displayed, press F9 **STOP** first.

```
SAMPLE MODE?

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

6. Does the top of the **F3-Run** window display **PRIMARY: SAMPLE ANALYSIS**?
   - If yes, press Esc.
   - If no, press F2 **START PRIMARY**.

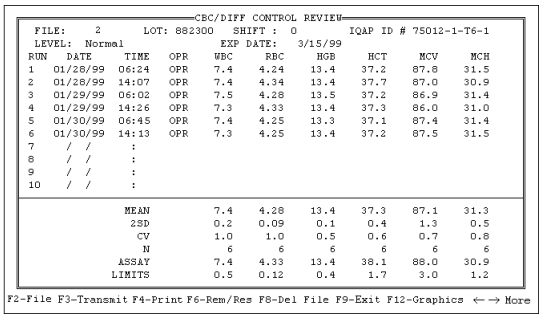
```
PRIMARY:     SAMPLE ANALYSIS

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

7. Mix the control tube according to package insert directions.
8. Place the control tubes in a cassette.
   - Control tubes must be clean and dry.
   - Bar-code labels must be visible through the top of the cassette.
   - Control tubes must fit securely.
   - Tube stoppers must not extend beyond the top of the cassette.
9. Place the cassette in the loading bay.
   - Results are placed automatically in the correct file as long as the instrument can read the bar code.
   - Results do not appear on the Run Samples screen.
   - If any result is out of control, an error message displays.



10. Check the results of the controls.
    a. Select **Controls ▸▸ Review or Report.**
    b. Check for H (High) or L (Low) beside the results.
       - If there are no H's or L's, results are within range.
       - If you see an H or L, go to Table 2.2. Follow the troubleshooting steps until you solve the problem.

       Note: For more information about **Review or Report,** see Heading 2.3
    c. Use F2 **File** to select other files to review.
11. Optional: To print your last control run, select **Controls ▸▸ Control Run**. Press F4 **Print**. Use F2 **File** to select other files to print.



CBC/DIFF CONTROL REVIEW

FILE: 2 LOT: 882300 SHIFT : 0 IQAP ID # 75012-1-T6-1
LEVEL: Normal EXP DATE: 3/15/99

RUN	DATE	TIME	OPR	WBC	RBC	HGB	HCT	MCV	MCH
1	01/28/99	06:24	OPR	7.4	4.24	13.4	37.2	87.8	31.5
2	01/28/99	14:07	OPR	7.4	4.34	13.4	37.7	87.0	30.9
3	01/29/99	06:02	OPR	7.5	4.28	13.5	37.2	86.9	31.4
4	01/29/99	14:26	OPR	7.3	4.33	13.4	37.3	86.0	31.0
5	01/30/99	06:45	OPR	7.4	4.25	13.3	37.1	87.4	31.4
6	01/30/99	14:13	OPR	7.3	4.25	13.4	37.2	87.5	31.5
7	/ /	:							
8	/ /	:							
9	/ /	:							
10	/ /	:							
		MEAN		7.4	4.28	13.4	37.3	87.1	31.3
		2SD		0.2	0.09	0.1	0.4	1.3	0.5
		CV		1.0	1.0	0.5	0.6	0.7	0.8
		N		6	6	6	6	6	6
		ASSAY		7.4	4.33	13.4	38.1	88.0	30.9
		LIMITS		0.5	0.12	0.4	1.7	3.0	1.2

F2-File F3-Transmit F4-Print F6-Rem/Res F8-Del File F9-Exit F12-Graphics ←→ More

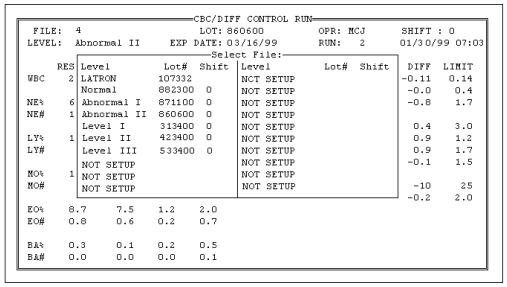
Table 2.2 When CBC/DIFF Control is Out of Limits

Possibility	Action
Improper mixing	Follow the instructions on the package insert. Rerun control.
Control file set up incorrectly	Make sure the assigned values and ranges match those on the control package insert. If in error, correct them by selecting **Special Functions ▸▸ Set Up ▸▸ Control Set Up.**
Chance (statistical outlier)	Rerun the control. If it is still "out," try the next possibility.
Change in the control	Try another vial or level of control. Follow directions on the package insert for proper handling.
Instrument change	Watch for normal sample flow. Call your Beckman Coulter Representative to help you troubleshoot abnormal operation.

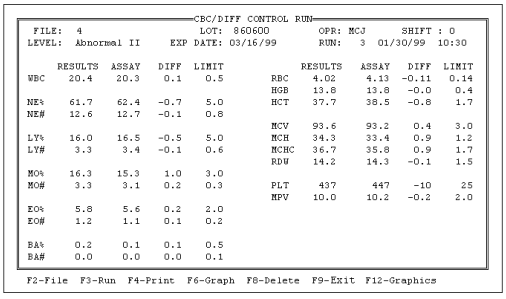
Cycling Commercial Cell Controls without Bar-Code Labels

1. Follow the directions on the cell control package insert for storage, preparation and mixing.
2. Access the appropriate Control Run screen:
   - at the Access screen, press F2 **RUN CONTROLS**

     OR
   - at the Main Menu, select **Controls ▸▸ Control Run**.
3. If the correct file does not appear
   a. Press F2 **File**.
   b. Move the cursor to highlight the correct file.
   c. Press Enter.



4. Press F3 **Run** F2 **START PRIMARY**.
5. Mix the control tube according to package insert directions.
6. Load the control tube into a cassette and place the cassette in the loading bay.
7. Wait until the control results appear. Check for H (High) or L (Low) beside the results.
   - If there are no H's or L's, results are within range. Go to step 8.
   - If you see an H or L, finish running any other levels of control then go to Table 2.2. Follow the troubleshooting steps until you solve the problem.
   - Optional: Press F4 to print the control results.



8. To display another level of control:
   a. Press F2 **File**.
   b. Move the cursor to highlight the appropriate file.
   c. Press Enter.
9. Repeat steps 5 through 8 for any remaining controls.

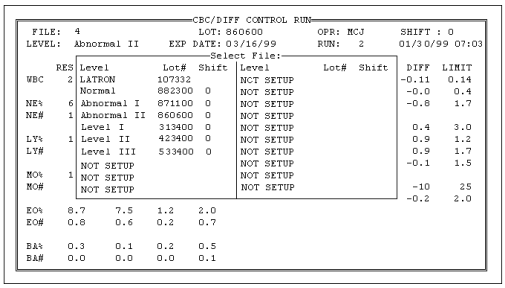
Cycling 5C Cell Control in the Secondary Mode

5C cell control is assayed only for Primary mode. If you use Secondary mode, your laboratory must determine its own means and expected ranges for each parameter.

IMPORTANT Blood detectors are inactive in Secondary mode. Sample and aspiration integrity are not checked. To avoid misleading results, ensure complete immersion of the aspirator tip in the sample. Do not remove the sample until you hear the beep.

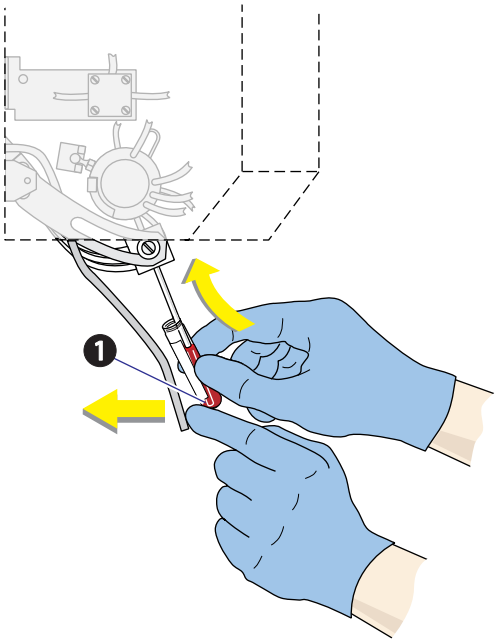
1. Follow the directions on the cell control package insert for storage, preparation and mixing.
2. Access the appropriate Control Run screen:
   - at the Access screen, press F2 **RUN CONTROLS**

     OR
   - at the Main Menu, select **Controls ▸▸ Control Run**.
3. If the correct file does not appear
   a. Press F2 **File**.
   b. Move the cursor to highlight the correct file.
   c. Press Enter.

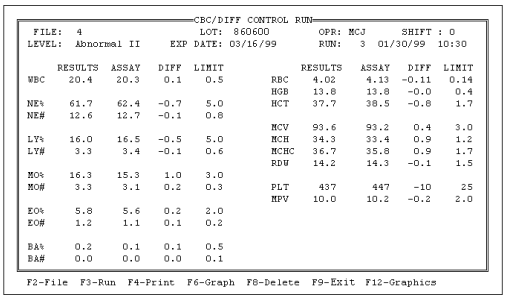


4. Press F3 **Run** F3 **SECONDARY**.
5. Mix the control tube according to package insert directions.

6. Cycle the control:
   a. Open the tube and immerse the aspirator tip ❶ into the sample.
   b. Press and release the sample bar.
   c. Remove the tube when you hear the beep.



7. Check for H (High) or L (Low) beside the results on the screen.
   - If there are no H's or L's, results are within range.
   - If you see an H or L, go to Table 2.2. Follow the troubleshooting steps until you solve the problem.
8. Optional: press F4 to print the control results.
9. Use F2 **File** to select other files and run additional levels of control as required.



CBC/DIFF CONTROL RUN

FILE: 4 LOT: 860600 OPR: MCJ SHIFT : 0
LEVEL: Abnormal II EXP DATE: 03/16/99 RUN: 3 01/30/99 10:30

	RESULTS	ASSAY	DIFF	LIMIT		RESULTS	ASSAY	DIFF	LIMIT
WBC	20.4	20.3	0.1	0.5	RBC	4.02	4.13	-0.11	0.14
					HGB	13.8	13.8	-0.0	0.4
NE%	61.7	62.4	-0.7	5.0	HCT	37.7	38.5	-0.8	1.7
NE#	12.6	12.7	-0.1	0.8					
					MCV	93.6	93.2	0.4	3.0
LY%	16.0	16.5	-0.5	5.0	MCH	34.3	33.4	0.9	1.2
LY#	3.3	3.4	-0.1	0.6	MCHC	36.7	35.8	0.9	1.7
					RDW	14.2	14.3	-0.1	1.5
MO%	16.3	15.3	1.0	3.0					
MO#	3.3	3.1	0.2	0.3	PLT	437	447	-10	25
					MPV	10.0	10.2	-0.2	2.0
EO%	5.8	5.6	0.2	2.0					
EO#	1.2	1.1	0.1	0.2					
BA%	0.2	0.1	0.1	0.5					
BA#	0.0	0.0	0.0	0.1					

F2-File F3-Run F4-Print F6-Graph F8-Delete F9-Exit F12-Graphics

COULTER Retic-C™ Cell Control

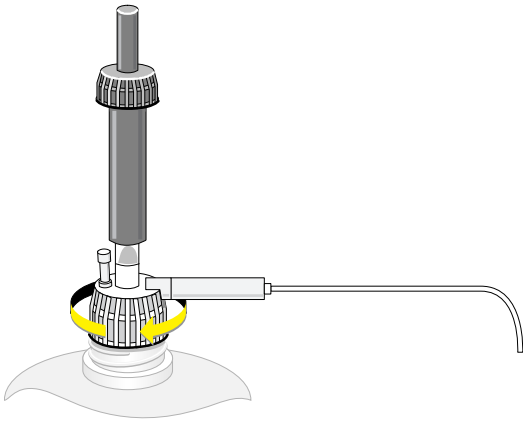
Retic-C cell control is a hematology reference control that monitors Beckman Coulter systems with reticulocyte technology using VCS (volume, conductivity, and light scatter). Use Retic-C cell controls, Levels I, II and III, with the COULTER ReticPrep™ Reagent kit.

IMPORTANT Modifications to the pre-prep procedures or failure to follow these instructions may lead to misleading or erroneous results. Perform the pre-prep procedures according to the instructions below.

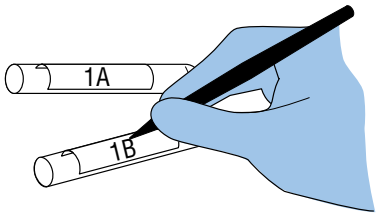
CAUTION Running whole blood or control through the aspirator probe while in the Retic mode can damage the system. Perform the pre-prep procedures according to the instructions below.

IMPORTANT Misleading results can occur if Retic-C cell control is not prepared properly. Follow the procedure on the package insert to properly warm, mix and prepare Retic-C cell control for analysis.

1. Make sure:
   a. Dispenser is fitted securely to the Reagent B bottle.
   b. Reagent fills the clear tubing without any bubbles.



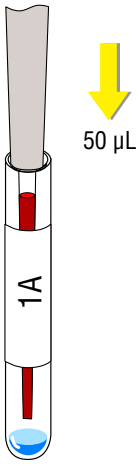
2. For each control tested, label two test tubes: "A" and "B."



IMPORTANT Dispensing Reagent A at an angle changes the dilution of the preparation. Dispense the drops of Reagent A vertically.

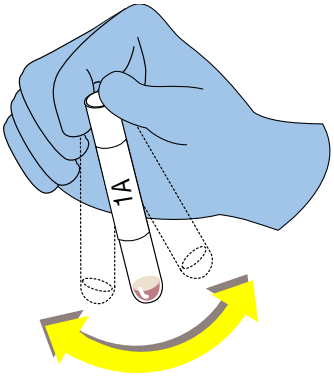
3. Place four drops of Reagent A into the test tube labeled "A."

4. Dispense 50 µL of well-mixed control into the tube labeled "A." Do not let the control run down the sides of the tube.



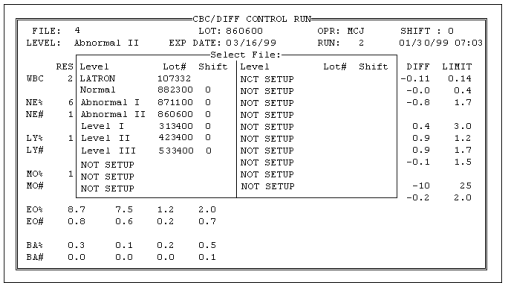
5. Gently mix tube "A."

   Prepare other levels of control using steps 1 through 5.



6. Let stand for at least 5 minutes at room temperature. Up to 60 minutes is allowable.
7. Access the appropriate Control Run screen:
   - at the Access screen, press F2 **RUN CONTROLS**

     OR
   - at the Main Menu, select **Controls** ▸▸ **Control Run**.
8. If the correct file does not appear
   a. Press F2 **File**.
   b. Move the cursor to highlight the correct file.
   c. Press Enter.

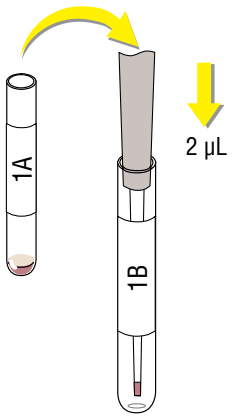


9. Press F3 **Run**
   F3 **CONTROL (SECONDARY)**

```
SAMPLE MODE ?

  F3 CONTROL (SECONDARY)
  F7 PURGE
  F8 RINSE
  F9 STOP

Select to change/ESC to continue
```

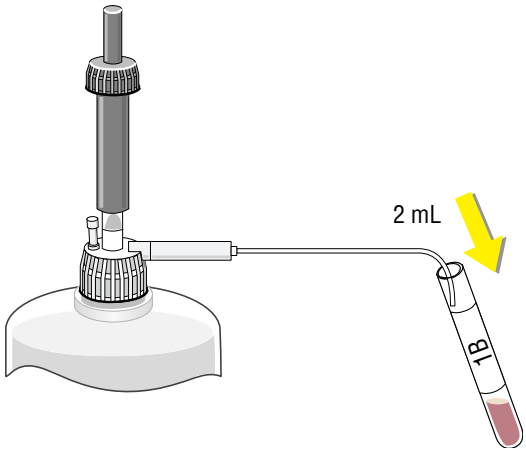
IMPORTANT To ensure accurate results, add the control-stain mixture directly to the bottom of the tube; do not allow control-stain mixture to run down the sides of the tube. To prevent drying of this small amount, proceed immediately to the next step.

10. Gently mix tube "A" again then transfer 2 µL of the control/stain mixture from tube "A" into the bottom of tube "B."



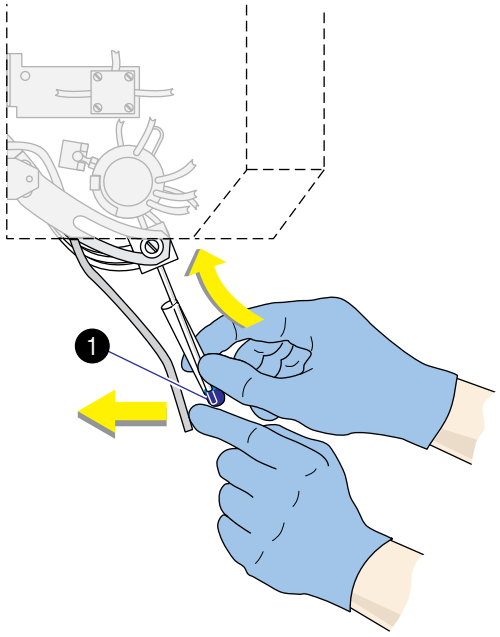
IMPORTANT To ensure accurate results, allow Reagent B to run down the side of the tube so that no foaming or bubbles occur, but rapidly enough to mix the control-stain mixture and Reagent B. Do not do any additional mixing.

11. Dispense Reagent B.
    a. Place tube "B" with the control-stain aliquot at a 30° angle under the tip of the Reagent B dispenser.
    b. Dispense 2 mL of Reagent B into the test tube "B." DO NOT MIX.



12. Wait 30 seconds.

13. After 30 seconds, analyze the control.
    a. Immerse the aspirator tip ❶ into the retic preparation.
    b. Press and release the sample bar.
    c. Remove the tube when you hear the beep.



14. Check for H (High) or L (Low) beside the results on the screen.
    - If there are no H's or L's, results are within expected range.
    - If you see an H or L, go to Table 2.3. Follow the troubleshooting steps until you solve the problem.

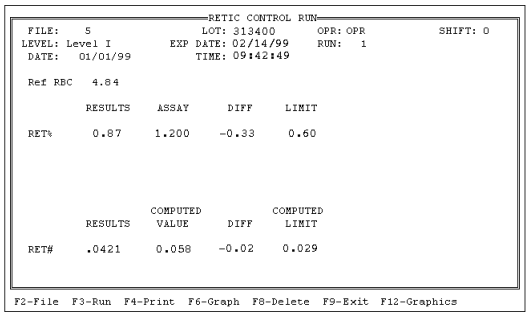


Table 2.3 When Retic Control is Out of Limits

Possibility	Action
Improper mixing or preparation of control	Follow the mixing instructions on the package insert and the preparation instructions in the manual. Make another preparation and rerun control.
Control file set up incorrectly	Make sure the assigned values and ranges match those on the control package insert. If in error, correct them by selecting **Special Functions ▸▸ Set Up ▸▸ Control Set Up.**
Chance (statistical outlier)	Rerun the control. If it is still "out", try the next possibility.
Change in the control or pre-prep reagents	Try another vial or level of control. Try new reagents A and B.
Instrument change	Call your Coulter Representative to help you troubleshoot abnormal operation.

2.3 CONTROL REVIEW OR REPORT

Select **Controls ▸▸ Review or Report**

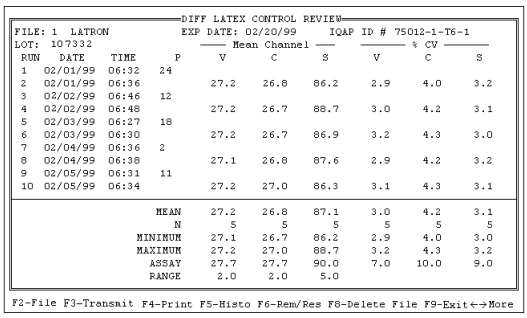
- Use to review and print:
  - Control results, cumulative statistics and histograms for LATEX files
  - Control results, cumulative statistics and graphics for CBC/DIFF and RETIC files
  - Control results and cumulative statistics for CBC files
- Use to transmit control results and cumulative statistics for any control file.
- Use to periodically check cumulative results for trends or shifts.

LATEX Control Review or Report

Use to review and print control results, cumulative statistics and histograms for LATEX files. Can also be used to transmit the data of the entire control file to a host computer.

Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.

Diff Latex Control Review screen



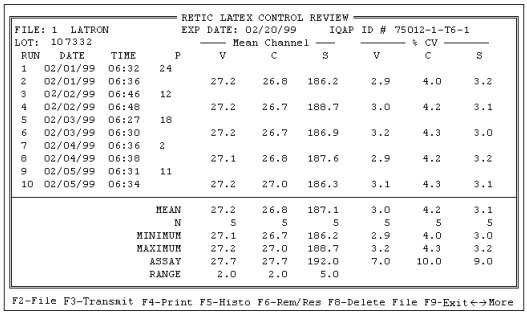
DIFF LATEX CONTROL REVIEW

FILE: 1 LATRON — EXP DATE: 02/20/99 — IQAP ID # 75012-1-T6-1
LOT: 107332 — Mean Channel — % CV

RUN	DATE	TIME	P	V	C	S	V	C	S
1	02/01/99	06:32	24						
2	02/01/99	06:36		27.2	26.8	86.2	2.9	4.0	3.2
3	02/02/99	06:46	12						
4	02/02/99	06:48		27.2	26.7	88.7	3.0	4.2	3.1
5	02/03/99	06:27	18						
6	02/03/99	06:30		27.2	26.7	86.9	3.2	4.3	3.0
7	02/04/99	06:36	2						
8	02/04/99	06:38		27.1	26.8	87.6	2.9	4.2	3.2
9	02/05/99	06:31	11						
10	02/05/99	06:34		27.2	27.0	86.3	3.1	4.3	3.1
			MEAN	27.2	26.8	87.1	3.0	4.2	3.1
			N	5	5	5	5	5	5
			MINIMUM	27.1	26.7	86.2	2.9	4.0	3.0
			MAXIMUM	27.2	27.0	88.7	3.2	4.3	3.2
			ASSAY	27.7	27.7	90.0	7.0	10.0	9.0
			RANGE	2.0	2.0	5.0			

F2-File F3-Transmit F4-Print F5-Histo F6-Rem/Res F8-Delete File F9-Exit↔More

Retic Latex Control Review screen



RETIC LATEX CONTROL REVIEW

FILE: 1 LATRON — EXP DATE: 02/20/99 — IQAP ID # 75012-1-T6-1
LOT: 107332 — Mean Channel — % CV

RUN	DATE	TIME	P	V	C	S	V	C	S
1	02/01/99	06:32	24						
2	02/01/99	06:36		27.2	26.8	186.2	2.9	4.0	3.2
3	02/02/99	06:46	12						
4	02/02/99	06:48		27.2	26.7	188.7	3.0	4.2	3.1
5	02/03/99	06:27	18						
6	02/03/99	06:30		27.2	26.7	186.9	3.2	4.3	3.0
7	02/04/99	06:36	2						
8	02/04/99	06:38		27.1	26.8	187.6	2.9	4.2	3.2
9	02/05/99	06:31	11						
10	02/05/99	06:34		27.2	27.0	186.3	3.1	4.3	3.1
			MEAN	27.2	26.8	187.1	3.0	4.2	3.1
			N	5	5	5	5	5	5
			MINIMUM	27.1	26.7	186.2	2.9	4.0	3.0
			MAXIMUM	27.2	27.0	188.7	3.2	4.3	3.2
			ASSAY	27.7	27.7	192.0	7.0	10.0	9.0
			RANGE	2.0	2.0	5.0			

F2-File F3-Transmit F4-Print F5-Histo F6-Rem/Res F8-Delete File F9-Exit↔More

Screen-Specific Function Keys:

F2 File
Displays all available files. Use ↑ and ↓ to select the file you need. Press Enter.

F3 Transmit
Transmits the data of the entire control file to a host computer.

F4 Print
Prints entire file in a line list format.

F5 Histo
Displays the volume, conductivity, and scatter (VCS) histograms screen.

F4 Print
Prints the screen.

F6 Additional Histo
Switches between DIFF and RETIC histograms.

F6 Rem/Res

Removes a highlighted run from the calculations. DEL appears in place of the run number. The statistics recalculate. Pressing F6 again restores the run and original statistics.

Note: This does not apply to Primer runs.

F8 Delete File

Deletes the current control file. Displays a message *You have asked to delete ENTIRE control file. Are you sure you want to delete?: No*. Press the Spacebar to select Yes or No then press Enter to confirm your choice.

F9 Exit

Exits to the Main Menu.

↔ More

Use → and ← to go back and forth between the Diff Latex Control Review screen and the Retic Latex Control Review screen.

Diff Latex Control Review screen

DIFF LATEX CONTROL REVIEW

FILE: 1 LATRON EXP DATE: 02/20/99 IQAP ID # 75012-1-T6-1
LOT: 107332

RUN	DATE	TIME	P	Mean Channel V	Mean Channel C	Mean Channel S	% CV V	% CV C	% CV S
1	02/01/99	06:32	24						
2	02/01/99	06:36		27.2	26.8	86.2	2.9	4.0	3.2
3	02/02/99	06:46	12						
4	02/02/99	06:48		27.2	26.7	88.7	3.0	4.2	3.1
5	02/03/99	06:27	18						
6	02/03/99	06:30		27.2	26.7	86.9	3.2	4.3	3.0
7	02/04/99	06:36	2						
8	02/04/99	06:38		27.1	26.8	87.6	2.9	4.2	3.2
9	02/05/99	06:31	11						
10	02/05/99	06:34		27.2	27.0	86.3	3.1	4.3	3.1
			MEAN	27.2	26.8	87.1	3.0	4.2	3.1
			N	5	5	5	5	5	5
			MINIMUM	27.1	26.7	86.2	2.9	4.0	3.0
			MAXIMUM	27.2	27.0	88.7	3.2	4.3	3.2
			ASSAY	27.7	27.7	90.0	7.0	10.0	9.0
			RANGE	2.0	2.0	5.0			

F2-File F3-Transmit F4-Print F5-Histo F6-Rem/Res F8-Delete File F9-Exit↔More

Retic Latex Control Review screen

RETIC LATEX CONTROL REVIEW

FILE: 1 LATRON EXP DATE: 02/20/99 IQAP ID # 75012-1-T6-1
LOT: 107332

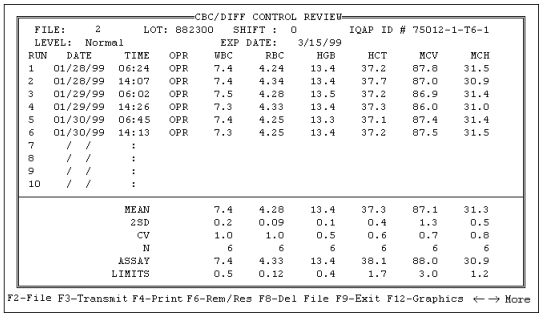
RUN	DATE	TIME	P	Mean Channel V	Mean Channel C	Mean Channel S	% CV V	% CV C	% CV S
1	02/01/99	06:32	24						
2	02/01/99	06:36		27.2	26.8	186.2	2.9	4.0	3.2
3	02/02/99	06:46	12						
4	02/02/99	06:48		27.2	26.7	188.7	3.0	4.2	3.1
5	02/03/99	06:27	18						
6	02/03/99	06:30		27.2	26.7	186.9	3.2	4.3	3.0
7	02/04/99	06:36	2						
8	02/04/99	06:38		27.1	26.8	187.6	2.9	4.2	3.2
9	02/05/99	06:31	11						
10	02/05/99	06:34		27.2	27.0	186.3	3.1	4.3	3.1
			MEAN	27.2	26.8	187.1	3.0	4.2	3.1
			N	5	5	5	5	5	5
			MINIMUM	27.1	26.7	186.2	2.9	4.0	3.0
			MAXIMUM	27.2	27.0	188.7	3.2	4.3	3.2
			ASSAY	27.7	27.7	192.0	7.0	10.0	9.0
			RANGE	2.0	2.0	5.0			

F2-File F3-Transmit F4-Print F5-Histo F6-Rem/Res F8-Delete File F9-Exit↔More

CBC/DIFF Control Review or Report

Use to review and print control results, cumulative statistics, and graphics for CBC/DIFF files. Can also be used to transmit the data of the entire control file to a host computer.

Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.



CBC/DIFF CONTROL REVIEW

FILE: 2 LOT: 882300 SHIFT : 0 IQAP ID # 75012-1-T6-1
LEVEL: Normal EXP DATE: 3/15/99

RUN	DATE	TIME	OPR	WBC	RBC	HGB	HCT	MCV	MCH
1	01/28/99	06:24	OPR	7.4	4.24	13.4	37.2	87.8	31.5
2	01/28/99	14:07	OPR	7.4	4.34	13.4	37.7	87.0	30.9
3	01/29/99	06:02	OPR	7.5	4.28	13.5	37.2	86.9	31.4
4	01/29/99	14:26	OPR	7.3	4.33	13.4	37.3	86.0	31.0
5	01/30/99	06:45	OPR	7.4	4.25	13.3	37.1	87.4	31.4
6	01/30/99	14:13	OPR	7.3	4.25	13.4	37.2	87.5	31.5
7	/ /	:							
8	/ /	:							
9	/ /	:							
10	/ /	:							
		MEAN		7.4	4.28	13.4	37.3	87.1	31.3
		2SD		0.2	0.09	0.1	0.4	1.3	0.5
		CV		1.0	1.0	0.5	0.6	0.7	0.8
		N		6	6	6	6	6	6
		ASSAY		7.4	4.33	13.4	38.1	88.0	30.9
		LIMITS		0.5	0.12	0.4	1.7	3.0	1.2

F2-File F3-Transmit F4-Print F6-Rem/Res F8-Del File F9-Exit F12-Graphics ← → More

Screen-Specific Function Keys:

F2 File
Displays all available files. Use ↑ and ↓ to select the file you need. Press Enter.

F3 Transmit
Transmits the data of the entire control file to a host computer.

F4 Print
Prints the entire control file in a line list format.

F6 Rem/Res
Removes a highlighted run from the calculations. DEL appears in place of the run number. The statistics recalculate. Pressing F6 again restores the run and original statistics.

F8 Del File
Deletes the current control file. Displays a message *You have asked to delete ENTIRE control file. Are you sure you want to delete?: No*. Press the Spacebar to select Yes or No then press Enter to confirm your choice.

F9 Exit
Exits to the Main Menu.

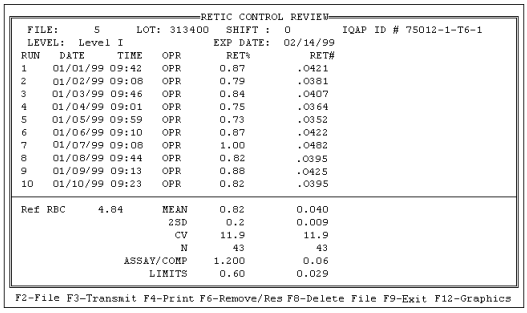
F12 Graphics
Displays scatterplot, histograms, and numeric results.

↔ More
Press ← or → to see additional parameters not currently displayed on the screen.

Retic Control Review or Report

Use to review and print control results, cumulative statistics, and graphics for Retic files. Can also be used to transmit the data of the entire control file to a host computer.

Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.


RETIC CONTROL REVIEW

FILE: 5 LOT: 313400 SHIFT : 0 IQAP ID # 75012-1-T6-1
LEVEL: Level I EXP DATE: 02/14/99

RUN	DATE	TIME	OPR	RET%	RET#
1	01/01/99	09:42	OPR	0.87	.0421
2	01/02/99	09:08	OPR	0.79	.0381
3	01/03/99	09:46	OPR	0.84	.0407
4	01/04/99	09:01	OPR	0.75	.0364
5	01/05/99	09:59	OPR	0.73	.0352
6	01/06/99	09:10	OPR	0.87	.0422
7	01/07/99	09:08	OPR	1.00	.0482
8	01/08/99	09:44	OPR	0.82	.0395
9	01/09/99	09:13	OPR	0.88	.0425
10	01/10/99	09:23	OPR	0.82	.0395

Ref RBC	4.84	MEAN	0.82	0.040
		2SD	0.2	0.009
		CV	11.9	11.9
		N	43	43
		ASSAY/COMP	1.200	0.06
		LIMITS	0.60	0.029

F2-File F3-Transmit F4-Print F6-Remove/Res F8-Delete File F9-Exit F12-Graphics

Screen-Specific Function Keys:

F2 File
Displays all available files. Use ↑ and ↓ to select the file you need. Press Enter.

F3 Transmit
Transmits the data of the entire control file to a host computer.

F4 Print
Prints the entire control file in a line list format.

F6 Remove/Res
Removes a highlighted run from the calculations. DEL appears in place of the run number. The statistics recalculate. Pressing F6 again restores the run and original statistics.

F8 Delete File
Deletes the current control file. Displays a message *You have asked to delete ENTIRE control file. Are you sure you want to delete?: No.* Press the Spacebar to select Yes or No then press Enter to confirm your choice.

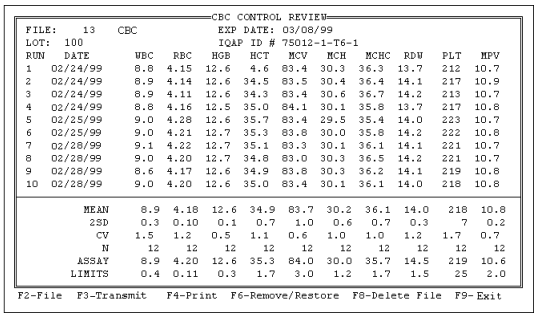
F9 Exit
Exits to the Main Menu.

F12 Graphics
Displays results in the Retic Control Analysis screen format.

CBC Control Review or Report

Use to review and print control results and cumulative statistics for CBC files. Can also be used to transmit the data of the entire control file to a host computer.

Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.



CBC CONTROL REVIEW

FILE: 13 CBC EXP DATE: 03/08/99
LOT: 100 IQAP ID # 7SO12-1-T6-1

RUN	DATE	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV
1	02/24/99	8.8	4.15	12.6	4.6	83.4	30.3	36.3	13.7	212	10.7
2	02/24/99	8.9	4.14	12.6	34.5	83.5	30.4	36.4	14.1	217	10.9
3	02/24/99	8.9	4.11	12.6	34.3	83.4	30.6	36.7	14.2	213	10.7
4	02/24/99	8.8	4.16	12.5	35.0	84.1	30.1	35.8	13.7	217	10.8
5	02/25/99	9.0	4.28	12.6	35.7	83.4	29.5	35.4	14.0	223	10.7
6	02/25/99	9.0	4.21	12.7	35.3	83.8	30.0	35.8	14.2	222	10.8
7	02/28/99	9.1	4.22	12.7	35.1	83.3	30.1	36.1	14.1	221	10.7
8	02/28/99	9.0	4.20	12.7	34.8	83.0	30.3	36.5	14.2	221	10.7
9	02/28/99	8.6	4.17	12.6	34.9	83.8	30.3	36.2	14.1	219	10.8
10	02/28/99	9.0	4.20	12.6	35.0	83.4	30.1	36.1	14.0	218	10.8
	MEAN	8.9	4.18	12.6	34.9	83.7	30.2	36.1	14.0	218	10.8
	2SD	0.3	0.10	0.1	0.7	1.0	0.6	0.7	0.3	7	0.2
	CV	1.5	1.2	0.5	1.1	0.6	1.0	1.0	1.2	1.7	0.7
	N	12	12	12	12	12	12	12	12	12	12
	ASSAY	8.9	4.20	12.6	35.3	84.0	30.0	35.7	14.5	219	10.6
	LIMITS	0.4	0.11	0.3	1.7	3.0	1.2	1.7	1.5	25	2.0

F2-File F3-Transmit F4-Print F6-Remove/Restore F8-Delete File F9-Exit

Screen-Specific Function Keys:

F2 File
Displays all available files. Use ↑ and ↓ to select the file you need. Press Enter.

F3 Transmit
Transmits the data of the entire control file to a host computer.

F4 Print
Prints the entire control file in a line list format.

F6 Remove/Restore
Removes a highlighted run from the calculations. DEL appears in place of the run number. The statistics recalculate. Pressing F6 again restores the run and original statistics.

F8 Delete File
Deletes the current control file. Displays a message *You have asked to delete ENTIRE control file. Are you sure you want to delete?: No*. Press the Spacebar to select Yes or No then press Enter to confirm your choice.

F9 Exit
Exits to the Main Menu.

2.4 CONTROL GRAPHS

Select **Controls ▸▸ Graphs**

Control results are plotted on Levey-Jennings graphs.

Review as necessary to check for shifts and trends.

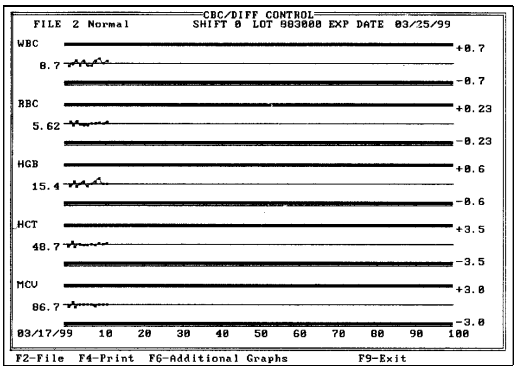
Screen-Specific Function Keys:

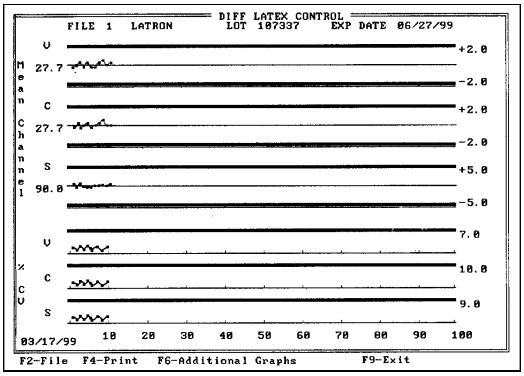
F2 File
Displays all available files. Use ↑ and ↓ to select the file you need. Press Enter.

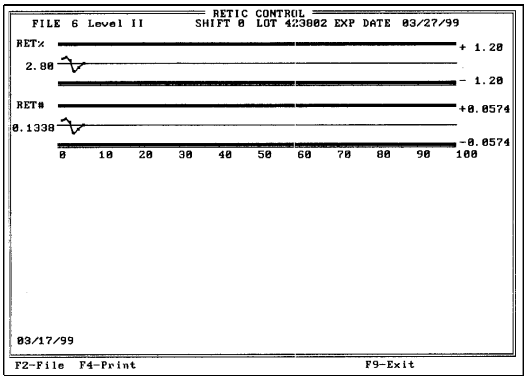
F4 Print
Prints all graphs for the file.

F6 Additional Graphs
See graphs of the other parameters. Retic has only one graph.

F9 Exit
Exits to the Main Menu.







Note: Each **Control Run** screen has the function F6 **Graph** which displays semi-quantitative graphs of the last 10 control samples for a quick quality control check. Press F6 several times until you have scrolled through the graphs of all of the parameters.

2.5 MODE TO MODE

Beckman Coulter recommends that you perform a mode to mode quality-control check at intervals established by your laboratory. Run a normal whole blood sample multiple times in both the Primary and Secondary modes and compare the mean results. For an N of 10, the mean results should compare within the limits listed below. If you use an N of less than 10, you will need to establish your own limits.

Secondary mode-to-Primary mode comparison limits for an N of 10 are:

WBC	$\pm$ 0.4 X 10^3 cells/µL or <5%, whichever is greater
RBC	$\pm$ 0.20 X 10^6 cells/µL or <2%, whichever is greater
Hgb	$\pm$ 0.3 g/dL or <2%, whichever is greater
Plt	$\pm$ 20 X 10^3 cells/µL or <7%, whichever is greater

Investigate any failure to recover values within expected limits. If you cannot resolve the problem, contact your Beckman Coulter Representative.

2.6 $\overline{X}_B$ ANALYSIS

$\overline{X}_B$ Theory

$\overline{X}_B$ analysis is a quality control method that monitors instrument performance by tracking the MCV, MCH and MCHC parameters of patient samples. The method uses the red blood cell indices because they tend to remain fairly stable and show little variance between patient samples.

Target Values

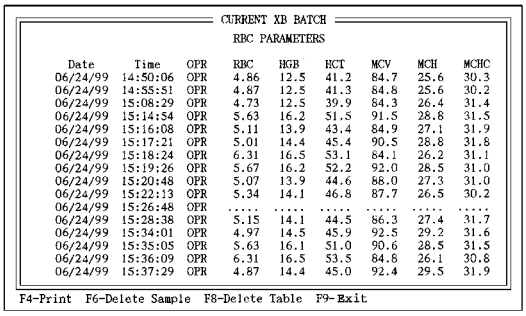
Dr. Brian Bull (the creator of $\overline{X}_B$ analysis) has determined the following target values for each index:

MCV - 89.5
MCH - 30.5
MCHC - 34.0

These constants were established using a general hospital population. Each laboratory should begin with these target values and then adjust them for their own patient population. $\overline{X}_B$ target values are set up in the DMS. See Chapter 6, Set Up, XB LIMITS.

Current XB Batch

Select **Sample Analysis ▸▸ XB ▸▸ Current XB Batch**


CURRENT XB BATCH

RBC PARAMETERS

Date	Time	OPR	RBC	HGB	HCT	MCV	MCH	MCHC
06/24/99	14:50:06	OPR	4.86	12.5	41.2	84.7	25.6	30.3
06/24/99	14:55:51	OPR	4.87	12.5	41.3	84.8	25.6	30.2
06/24/99	15:08:29	OPR	4.73	12.5	39.9	84.3	26.4	31.4
06/24/99	15:14:54	OPR	5.63	16.2	51.5	91.5	28.8	31.5
06/24/99	15:16:08	OPR	5.11	13.9	43.4	84.9	27.1	31.9
06/24/99	15:17:21	OPR	5.01	14.4	45.4	90.5	28.8	31.8
06/24/99	15:18:24	OPR	6.31	16.5	53.1	84.1	26.2	31.1
06/24/99	15:19:26	OPR	5.67	16.2	52.2	92.0	28.5	31.0
06/24/99	15:20:48	OPR	5.07	13.9	44.6	88.0	27.3	31.0
06/24/99	15:22:13	OPR	5.34	14.1	46.8	87.7	26.5	30.2
06/24/99	15:26:48	OPR	.....	.....	.....	.....	.....	.....
06/24/99	15:28:38	OPR	5.15	14.1	44.5	86.3	27.4	31.7
06/24/99	15:34:01	OPR	4.97	14.5	45.9	92.5	29.2	31.6
06/24/99	15:35:05	OPR	5.63	16.1	51.0	90.6	28.5	31.5
06/24/99	15:36:09	OPR	6.31	16.5	53.5	84.8	26.1	30.8
06/24/99	15:37:29	OPR	4.87	14.4	45.0	92.4	29.5	31.9

F4-Print F6-Delete Sample F8-Delete Table F9- Exit

When XB is ON, the DMS stores the RBC parameter results of all patient samples as they are cycled. These results display on the Current XB Batch screen. When a batch of 20 samples is collected, the DMS performs XB analysis and calculates the batch mean for MCV, MCH and MCHC. Partial aspirations are not included.

Screen-Specific Function Keys:

F4 Print
Prints the table.

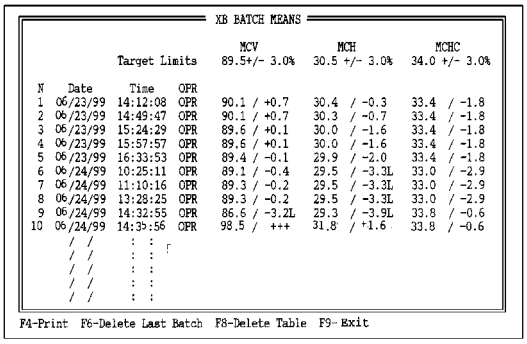
F6 Delete Sample
Deletes a single sample from the current batch. A maximum of 5 samples may be deleted.

F8 Delete Table
Deletes the entire table.

F9 Exit
Exits to the Main Menu.

XB Batch Means

Select **Sample Analysis ▸▸ XB ▸▸ XB Batch Means**

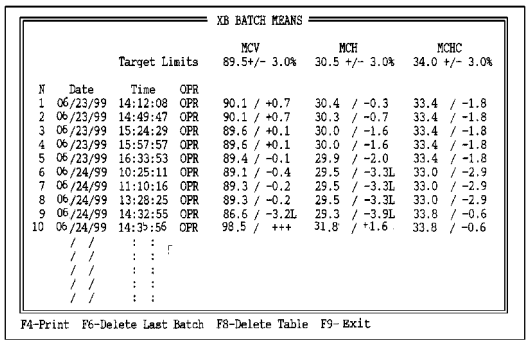

XB BATCH MEANS

N	Date	Time	OPR	MCV	MCH	MCHC
	Target Limits			89.5+/- 3.0%	30.5 +/- 3.0%	34.0 +/- 3.0%
1	06/23/99	14:12:08	OPR	90.1 / +0.7	30.4 / -0.3	33.4 / -1.8
2	06/23/99	14:49:47	OPR	90.1 / +0.7	30.3 / -0.7	33.4 / -1.8
3	06/23/99	15:24:29	OPR	89.6 / +0.1	30.0 / -1.6	33.4 / -1.8
4	06/23/99	15:57:57	OPR	89.6 / +0.1	30.0 / -1.6	33.4 / -1.8
5	06/23/99	16:33:53	OPR	89.4 / -0.1	29.9 / -2.0	33.4 / -1.8
6	06/24/99	10:25:11	OPR	89.1 / -0.4	29.5 / -3.3L	33.0 / -2.9
7	06/24/99	11:10:16	OPR	89.3 / -0.2	29.5 / -3.3L	33.0 / -2.9
8	06/24/99	13:28:25	OPR	89.3 / -0.2	29.5 / -3.3L	33.0 / -2.9
9	06/24/99	14:32:55	OPR	86.6 / -3.2L	29.3 / -3.9L	33.8 / -0.6
10	06/24/99	14:39:56	OPR	98.5 / +++	31.8 / +1.6	33.8 / -0.6
	/ /	: :				
	/ /	: :				
	/ /	: :				
	/ /	: :				
	/ /	: :				

F4-Print F6-Delete Last Batch F8-Delete Table F9- Exit

Use to view the calculated means for each batch of 20 samples collected. MCV, MCH and MCHC means are calculated.

Screen-Specific Function Keys:



F4 Print
Prints the table.

F6 Delete Last Batch
Deletes the last batch. Delete only if the batch is so badly skewed because of non-random sampling or an instrument problem that it will adversely affect many later batches.

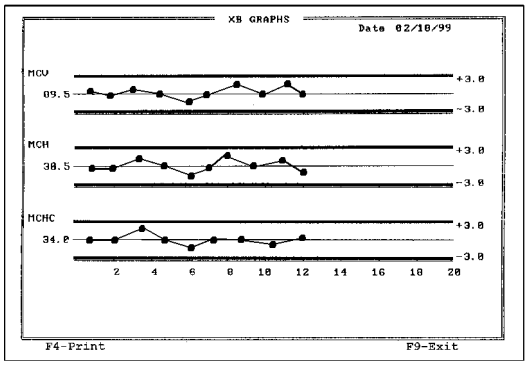
F8 Delete Table
Deletes the entire table.

F9 Exit
Exits to the Main Menu.

XB Graphs

Select Sample Analysis ▸▸ XB ▸▸ XB Graphs

Use to view the graphs of the last 20 MCV, MCH, and MCHC XB batch means.



Screen-Specific Function Keys:

F4 Print
Prints the graphs.

F9 Exit
Exits to the Main Menu.

Note: For more information about XB, including results interpretation and troubleshooting, refer to the Operator's Training Guide.

2.7 IQAP

The Interlaboratory Quality Assurance Program (IQAP) both complements and enhances your laboratory's in-house quality control. It is a service offered to users of Beckman Coulter Hematology cell controls and calibrators worldwide. The IQAP manual (PN 4206266) presents information on program enrollment, data entry, the IQAP report, quality control concepts, and answers to the most commonly asked questions about the program.

The IQAP program is comprehensive and easy to use. For each set of data you submit, you will receive a personalized report. It presents summaries of your results and compares them to those of the peer group (pool).

You should submit your control data to IQAP as soon as you finish the control lots (typically once a month). Only submit data from control files you have not previously submitted. If you keep several months of control data in your DMS, indicate "NO" in the "Report" column for all previously submitted files when you get to that part of the download program.

The procedure presented below is a summary of how to download your control files to a diskette provided by IQAP. Refer to the Data Entry Instructions document included with the IQAP manual for a more detailed procedure if necessary.

1. At the DMS, verify that your IQAP identification number is entered correctly. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ IQAP ID#**. Correct if necessary.
2. At the DMS, verify that your instrument's serial number and institution information is entered correctly. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Institution**. Correct if necessary.
3. Label the IQAP diskette with the identification label supplied by IQAP.
4. Insert the IQAP diskette into the DMS diskette drive.
5. Turn the computer power OFF. Wait 15 seconds then turn the computer power ON. See the illustration of the computer in Chapter 1 for the location of the power On/Off switch.
6. Carefully follow the screen instructions to select and download the appropriate control files.
7. Once you reach the final screen that indicates that your HmX successfully downloaded the control files, it will direct you to:
   - remove the diskette from the diskette drive
   - place the diskette in the return mailer provided by IQAP and send immediately
   - reset the system using the Standby/Reset switch at the lower left corner of the instrument. Refer to the illustration and procedure in the Special Procedures and Troubleshooting manual if necessary.

If you are unable to download control data due to diskette failure, you can submit your data by filling out special data entry forms provided by IQAP. These forms have your institution demographics and IQAP identification number preprinted on them. You should keep a few of these forms on hand at all times for backup purposes. The instructions for filling out these forms are presented in the IQAP manual.

2.8 DIFFERENTIAL COMPARISON PROCEDURE

You can perform manual differentials as a measure of QC practice or as recommended by your laboratory, state and federal protocol. See the Diff Comparison procedure in the Reference manual.

3.1 CBC/DIFF SPECIMEN COLLECTION

Collect whole blood in a salt of EDTA according to procedures in:[1,2,3]

- NCCLS publication H4-A3,[4]
- NCCLS publication H3-A3.[5]

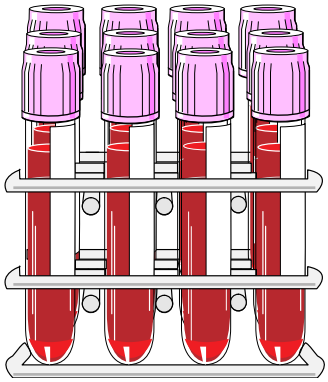
IMPORTANT If you do whole-blood calibration, you must use the same salt of EDTA for patient samples that you use for calibration. If you use a different salt of EDTA, sample results may be misleading.

All performance claims and validation studies have been based on the use of K_3EDTA. K_2EDTA shows no significant differences for CBC and differential results generated by instruments using VCS technology. If you use another anticoagulant, verify accuracy and precision data on your sample base.

Sample tubes cycled in the Primary mode must contain a minimum of 1.0 mL sample with the proper proportion of blood to anticoagulant. Sample tubes must contain enough air space for the sample to mix properly.

3.2 CBC/DIFF SPECIMEN STORAGE

- Refer to NCCLS publication H18-A for sample handling and storage.[6]
- Run within 24 hours of drawing.
- Store capped at room temperature.

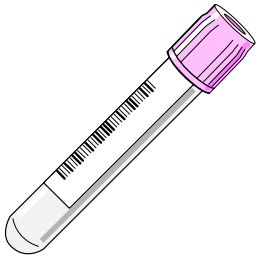


3.3 BAR-CODE LABELING

IMPORTANT Blood, scratches and powder from gloves reduces bar-code read rate. Keep the bar-code label free of blood, scratches and powder from gloves to maintain a high-read rate.

Place the bar-code label on the sample tube.

- Place the end of the label flush with the stopper.



- The bars on the label must be parallel to the stopper. If the label is skewed more than 5°, the scanner may not read it.

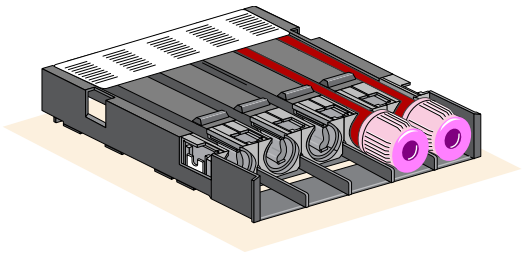
- Do not cover the bottom of the tube with the bar-code label or else the scanner will not be able to distinguish the sample tube label from the cassette label.

3.4 CASSETTES

Types

There are two sizes of cassettes:

- Universal - gray colored inserts.
  These cassettes hold tubes with an outer diameter of 10-13mm.
- 16mm - black inserts.
  These cassettes hold tubes with an outer diameter of 16mm.



Loading Tubes

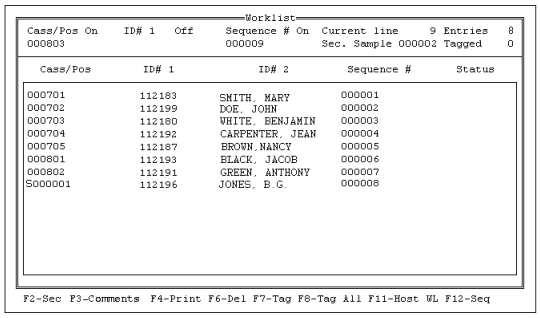
WARNING Risk of blood spills occurs when tubes fall or are pierced off center. Insertion of oversized objects, such as large tubes or fingers, into a universal cassette may cause the cassette clips to become stuck open or to not function properly. This can cause the tubes to fall out of the cassette or be pierced off center. Do not insert any object into a universal cassette other than the appropriately-sized tubes.

- Only use 10 to 13 mm o.d. tubes in the universal cassette with gray inserts. Do not insert large tubes (16 mm o.d.) into the universal cassette with gray inserts.
- Only use 16 mm o.d. tubes in the cassette with black inserts. Do not insert small or medium tubes (10 to 13 mm o.d.) into the cassette with black inserts.
- When loading the tubes into the cassette, verify that the tubes fit securely.
- Do not insert any tube into a cassette with the cap end first. This could cause the tube to break or the needle to bend.
- Tubes must not extend beyond the cassette.
- No object other than the tubes intended for the respective cassette should be inserted into a cassette.

3.5 PREASSIGNING THE WORKLIST

If using this option, assign samples to the Worklist now.

See Heading 3.12, Worklist at the end of this chapter for more information and procedures.



3.6 SAMPLE INTEGRITY CHECKS

In Primary mode, the system checks each sample aspiration using dual sensors, called blood detectors, which monitor the blood before and after it passes through the Blood Sampling Valve (BSV). These blood detectors optically sense air bubbles, diluent, and blood. As an indication of a good aspiration, the system looks for blood in both detectors. If the detectors optically identify bubbles in the sample, the instrument pierces the tube a second time. If the second aspiration contains bubbles, the instrument reports a partial aspiration. Bubbles or air may be present for various reasons, such as short sample aspirations or blockages in the aspiration pathway. Single dots (•••••) and *PART. ASP* are reported instead of numeric results when a partial aspiration occurs. Samples that generate multiple partial aspiration messages should be evaluated for specimen quality according to laboratory's protocol.

Samples with very low hemoglobin results may give partial aspirations when run in the Primary mode because the blood detectors do not recognize the sample as being blood. To obtain results, cycle the sample in the Secondary mode.

3.7 CYCLING SAMPLES IN THE PRIMARY MODE

IMPORTANT Poor quality specimens may require inspection and special attention. Specimens that may contain fibrin, cell fragments or other debris, or have been difficult to collect, such as, pediatric or oncology specimens may require special handling.

The HmX Hematology Analyzer with Autoloader is an automated cell counter that uses triplicate counting with strict voting criteria, and has proprietary flagging algorithms to confirm parameter results prior to reporting. Rarely, a transient or partial aperture blockage may not be detected by any of these processes. A partial aperture blockage may cause erroneous results, such as, WBC count lower than what is actually present.

As with any analysis method in which a specimen of suspect quality is used, particular attention should be given to the results. Verify the accuracy of results that are flagged and review all results that exceed your laboratory's action limits.

IMPORTANT A printer malfunction could cause you to report erroneous results. Check all printers attached to your HmX Hematology Analyzer with Autoloader. Make sure they are working properly and all numbers are printing correctly.

IMPORTANT Operating the HmX Hematology Analyzer with Autoloader with open doors or panels introduces electrical interference which can cause misleading results. Operate the HmX Hematology Analyzer with Autoloader with all doors and panels closed.

IMPORTANT Running out of reagent will cause erroneous results. The reagent sensors are designed to alert you before you run out. If you disable reagent sensors, the message *Reagent Sensors Off* appears on the screen and on graphic printouts. Carefully monitor the reagent's level if you ever disable its sensor.

1. Does *SELECT FUNCTION* appear at the lower right corner of the DMS screen?
   - If no, go to step 2.
   - If yes, continue with this step.

   a. Access the Run Samples screen:
      - at the Access screen, press [F1] **RUN SAMPLES**

        OR
      - at the Main Menu, select **Sample Analysis ▸▸ Run Samples**

   b. The instrument automatically prepares itself to run in the Primary mode, DIFF ON. Do you want DIFF ON?
      - If yes, go to step 6.
      - If no, press [F3] **Run**, [F9] **STOP**, [F6] **DIFF ON/OFF**, [F2] **START PRIMARY**. Go to step 6.

2. Access the Run Samples screen:
   - at the Access screen, press F1 **RUN SAMPLES**

     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Run Samples**
3. Press F3 **Run**.
4. If necessary, press F6 **DIFF ON/OFF** to change the DIFF setting.

   Note: If **SAMPLE MODE?** is not displayed, press F9 **STOP** first.

```
SAMPLE MODE?

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

5. Does the top of the **F3-Run** window display **PRIMARY: SAMPLE ANALYSIS**?
   - If yes, press Esc
   - If no, press F2 **START PRIMARY**

```
PRIMARY:     SAMPLE ANALYSIS

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

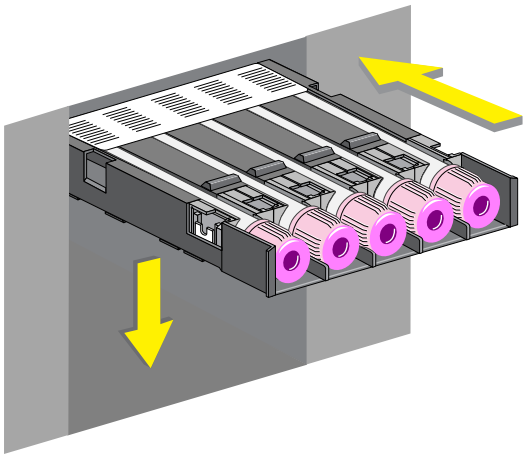
6. If necessary, set up your run samples options:
   a. Press F5 **Optns**.
   b. Press the corresponding function keys to set up your options.
   c. Press Esc to exit.

   Note: For detailed information about these options, refer to Chapter 1, Heading 1.5, RUN SAMPLES SCREEN OPTIONS.

```
F2   XB:     ON N=2 IN
F4   DB:     ON
F5   Print:  NONE
F6   Host:   OFF
F7   Display only: OFF
F8   Operator: OPR
F11  B&W screen print
F12  Color screen print
```

7. Place well mixed sample tubes in a cassette.
   - Tubes must be clean and dry.
   - Bar-code labels must be visible through the top of the cassette.
   - Tubes must fit securely.
   - Tube stoppers must not extend beyond the top of the cassette.

8. Place the cassette in the loading bay.
   - You can load up to five cassettes at one time.
   - Remove cassettes from the unloading bay on the left before they stack more than five high.



9. Review the results. Refer to Chapter 4, Data Review, for information on the Run Samples screen, scatterplots, histograms, parameter codes and flags and messages. Verify all sample ID entries before reporting results.

3.8 CYCLING STAT SAMPLES USING THE SECONDARY MODE

This procedure allows you to momentarily interrupt Primary mode processing to run a STAT sample in the Secondary mode.

IMPORTANT Blood detectors are inactive in Secondary mode. Sample and aspiration integrity are not checked. To avoid misleading results, ensure complete immersion of the aspirator tip in the sample. Do not remove the sample until you hear the beep.

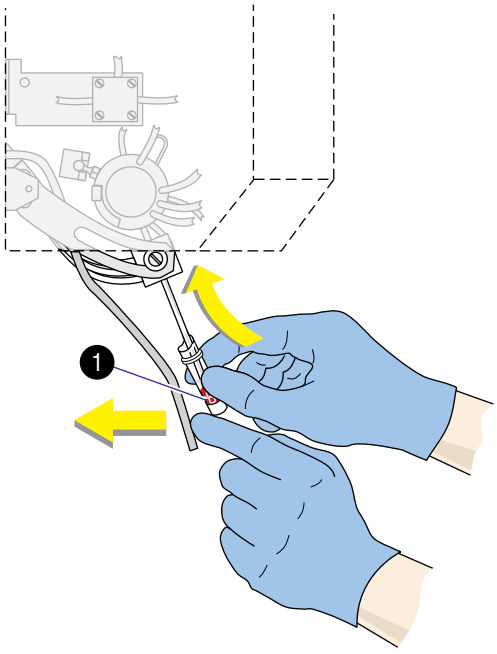
1. At the Run Samples screen, press F3 **Run**.
2. Press F3 **SECONDARY**.

   Note: The Autoloader bed continues to rock while the STAT sample is cycled.

```
PRIMARY:     SAMPLE ANALYSIS

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

3. Identify the sample:
   - Enter 1 to 16 alphanumeric characters then press Enter.
4. Mix the sample.

5. Cycle the sample:
   a. Open the tube and immerse the aspirator tip ❶ into the sample.
   b. Press and release the sample bar.
   c. Remove the tube when you hear the beep.



6. Repeat steps 3 through 5 for any other STAT samples.
7. When finished running the STAT(s), press F3 **Run** F2 **START PRIMARY** to resume Primary mode processing.

3.9 CYCLING SAMPLES IN THE SECONDARY MODE

IMPORTANT Poor quality specimens may require inspection and special attention. Specimens that may contain fibrin, cell fragments or other debris, or have been difficult to collect, such as, pediatric or oncology specimens may require special handling.

The HmX Hematology Analyzer with Autoloader is an automated cell counter that uses triplicate counting with strict voting criteria, and has proprietary flagging algorithms to confirm parameter results prior to reporting. Rarely, a transient or partial aperture blockage may not be detected by any of these processes. A partial aperture blockage may cause erroneous results, such as, WBC count lower than what is actually present.

As with any analysis method in which a specimen of suspect quality is used, particular attention should be given to the results. Verify the accuracy of results that are flagged and review all results that exceed your laboratory's action limits.

IMPORTANT Blood detectors are inactive in Secondary mode. Sample and aspiration integrity are not checked. To avoid misleading results, ensure complete immersion of the aspirator tip in the sample. Do not remove the sample until you hear the beep.

1. Access the Run Samples screen:
   - at the Access screen, press F1 **RUN SAMPLES**

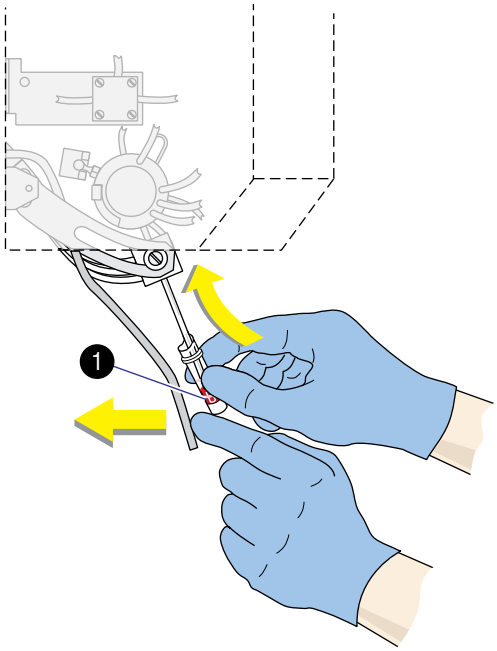
     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Run Samples**
2. Press F3 **Run**.
3. If necessary, press F6 **DIFF ON/OFF** to change the DIFF setting.

   Note: If **SAMPLE MODE?** is not displayed, press F9 **STOP** first.
4. Press F3 **SECONDARY**.

```
SAMPLE MODE?

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

5. Identify the sample:
   - Enter 1 to 16 alphanumeric characters then press Enter.

6. Mix according to the tube manufacturer's instructions.
7. Cycle the sample:
   a. Open the tube and immerse the aspirator tip ❶ into the sample.
   b. Press and release the sample bar.
   c. Remove the tube when you hear the beep.



8. Review the results. Refer to Chapter 4, Data Review, for information on the Run Samples screen, scatterplots, histograms, parameter codes and flags and messages.

3.10 CYCLING SAMPLES IN THE PREDILUTE MODE

Use the Predilute mode to do a repeat analysis of microcollection samples when less than 125 µL of sample remains. Only CBC results are reported on a Predilute mode sample.

The Predilute mode requires a 1:3 (X3) dilution. The HmX Hematology Analyzer automatically calculates the correct results based on a times three dilution.

You cannot use the Predilute mode to determine overrange counts that were reported +++++. To determine overrange counts, make the appropriate dilution, cycle in the Secondary mode, then multiply the results by the dilution factor.

IMPORTANT Poor quality specimens may require inspection and special attention. Specimens that may contain fibrin, cell fragments or other debris, or have been difficult to collect, such as, pediatric or oncology specimens may require special handling.

The HmX Hematology Analyzer with Autoloader is an automated cell counter that uses triplicate counting with strict voting criteria, and has proprietary flagging algorithms to confirm parameter results prior to reporting. Rarely, a transient or partial aperture blockage may not be detected by any of these processes. A partial aperture blockage may cause erroneous results, such as, WBC count lower than what is actually present.

As with any analysis method in which a specimen of suspect quality is used, particular attention should be given to the results. Verify the accuracy of results that are flagged and review all results that exceed your laboratory's action limits.

---

1. Access the Run Samples screen:
   - at the Access screen, press F1 **RUN SAMPLES**

     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Run Samples**.

2. Press F3 **Run**.
3. Press F4 **PREDILUTE CBC**.

```
SAMPLE MODE?

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

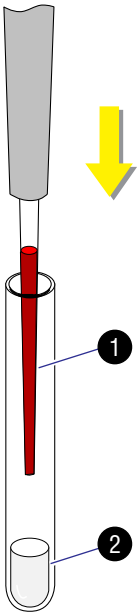
IMPORTANT Blood detectors are inactive in Predilute mode. Sample and aspiration integrity are not checked. To avoid misleading results, ensure complete immersion of the aspirator tip in the dilution. Do not remove the tube until you hear the beep.

4. Label a clean empty tube with an ID number.

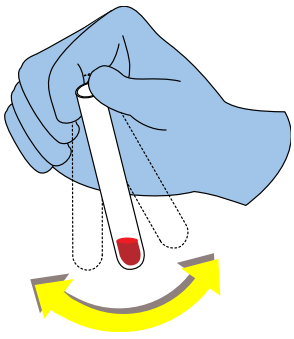
5. Make an accurate 1:3 (X3) dilution of the sample. Pipet a minimum of:
   - 50 µL of well-mixed, fresh whole blood ❶
   - 100 µL of diluent ❷

   into a tube.

   Note: Use larger volumes of diluent and blood, if available, to minimize the possibility of short sampling the dilution. Be sure to maintain the proper proportions for a times three dilution (one part blood, two parts diluent).



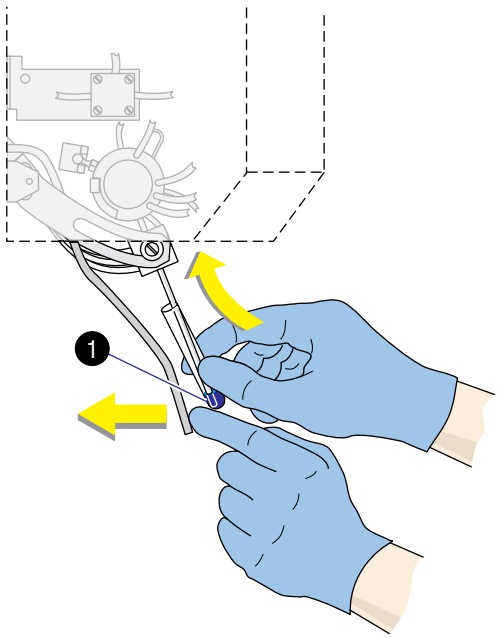
6. Mix the sample gently but thoroughly.



7. Enter 1 to 16 alphanumeric characters to identify the sample then press Enter.

IMPORTANT Incomplete aspiration will cause erroneous results. Tilt the tube as shown to ensure full aspiration.

8. Cycle the dilution:
   a. Immerse the aspirator tip ❶ into the dilution.
   b. Press and release the sample bar.
   c. Remove the tube when you hear the beep.



9. Use these results to compare to and confirm the original results of the microsample.

3.11 CYCLING SAMPLES IN THE RETIC MODE

Retic Specimen Collection

Collect whole blood in a salt of EDTA according to procedures in:

- NCCLS publication H4-A3, or
- NCCLS publication H3-A3.

Use of other anticoagulants can give misleading results.

Retic Specimen Storage

Store specimens capped and:

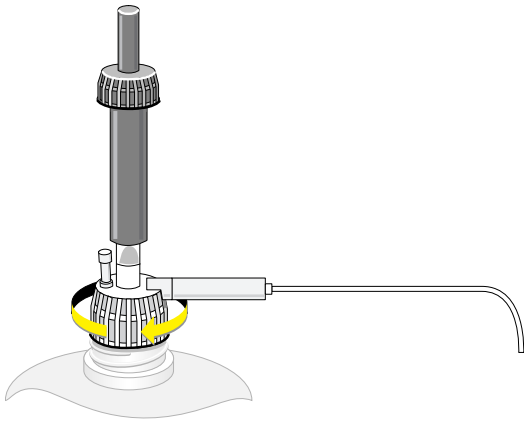
- If stored at room temperature, run within 8 hours.
- If stored refrigerated (2-8°C; 36-46°F), run within 24 hours.

Retic Sample Preparation

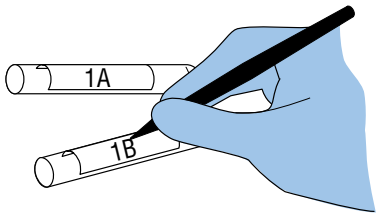
CAUTION Running whole blood or control through the aspirate probe while in the Retic mode can damage the system. Perform the pre-prep procedures according to the instructions below.

IMPORTANT Modifications to the pre-prep procedures or failure to follow these instructions may lead to misleading or erroneous results. Perform the pre-prep procedures according to the instructions below.

1. Make sure:
   a. Dispenser is fitted securely to the Reagent B bottle.
   b. Reagent fills the clear tubing without any bubbles.



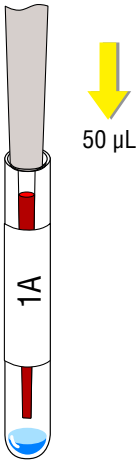
2. For each patient sample tested, label two test tubes: "A" and "B."



IMPORTANT Dispensing Reagent A at an angle changes the dilution of the preparation. Dispense the drops of Reagent A vertically.

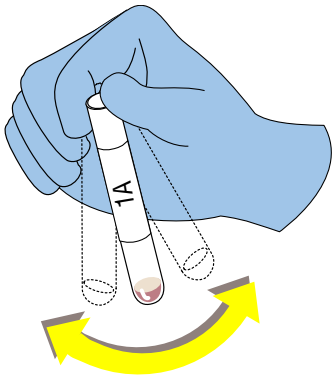
3. Place four drops of Reagent A into the test tube labeled "A."

4. Dispense 50 µL of well-mixed sample into the tube labeled "A." Do not let the blood run down the sides of the tube.



5. Gently mix tube "A."

   Prepare other patient samples using steps 1 through 5.



6. Let stand for at least 5 minutes at room temperature. Up to 60 minutes is allowable.

Retic Sample Analysis

1. Access the Run Samples screen:
   - at the Access screen, press F1 **RUN SAMPLES**

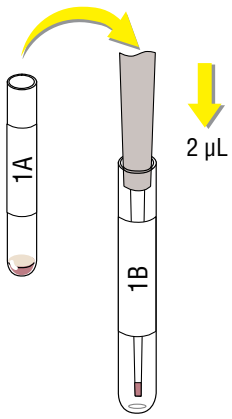
     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Run Samples**

2. Press F3 **Run**.
3. Press F5 **RETIC**.

```
SAMPLE MODE?

    F2 START PRIMARY
    F3 SECONDARY
    F4 PREDILUTE CBC
    F5 RETIC
    F6 DIFF ON/OFF
    F7 PURGE
    F8 RINSE
    F9 STOP
    DIFF: ON
    BLOOD DET: ON
Select to change/ESC to continue
```

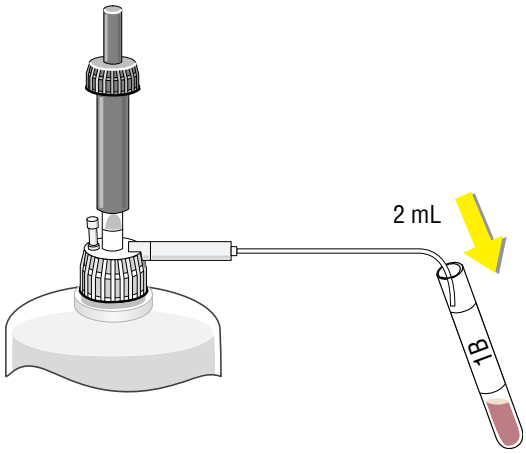
IMPORTANT To ensure accurate results, add the blood-stain mixture directly to the bottom of the tube; do not allow the blood-stain mixture to run down the sides of the tube. To prevent drying of this small amount, proceed immediately to the next step.

4. Gently mix tube "A" again then transfer 2 µL of the blood/stain mixture from tube "A" into the bottom of tube "B."



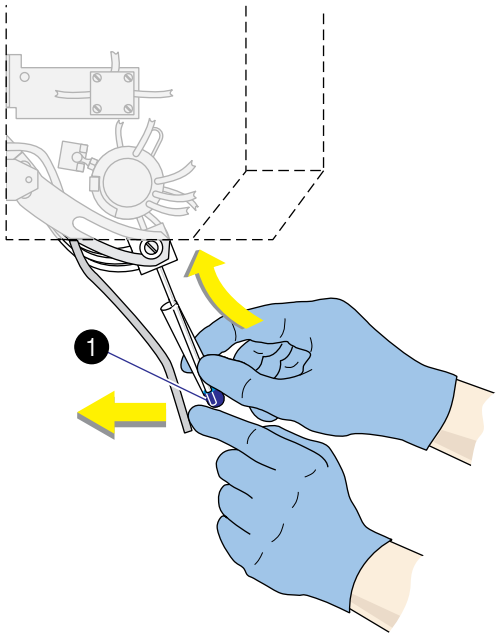
IMPORTANT To ensure accurate results, allow Reagent B to run down the side of the tube so that no foaming or bubbles occur, but rapidly enough to mix the blood-stain mixture and Reagent B. Do not do any additional mixing.

5. Dispense Reagent B.
   a. Place tube "B" with the blood-stain aliquot at a 30° angle under the tip of the Reagent B dispenser.
   b. Dispense 2 mL of Reagent B into the test tube "B." DO NOT MIX.

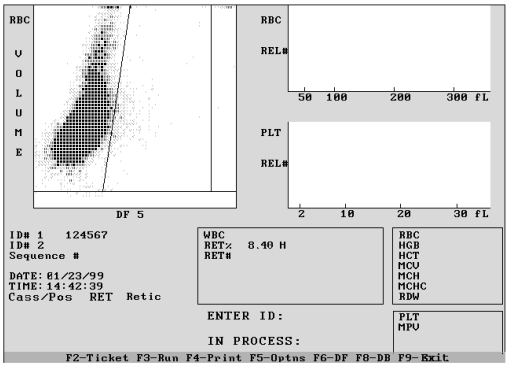


6. Wait 30 seconds.
   While you wait, enter the sample's identification. Type 1-16 alphanumeric characters then press Enter.

7. After 30 seconds, analyze the sample.
   a. Immerse the aspirator tip ❶ into the retic preparation.
   b. Press and release the sample bar.
   c. Remove the tube when you hear the beep.



8. Review the results. Refer to Chapter 4, Data Review, for information on the retic scatterplot and parameter codes and flags.



9. If you report RET#:
   a. Look up your retic result in Database Query.
   b. Press F3 **Edit**.
   c. Move your cursor to the RBC field and enter the patient's RBC result from that same sample.

   The system automatically calculates the RET#. An **E** appears next to the RBC and an **e** next to the RET#.
10. To print a graphic report including the RET#:
    a. Press Esc.
    b. Press F12 to display the graphic report.
    c. Press F4 to print.

3.12 WORKLIST

The purpose of the Worklist is to assign additional sample identifiers such as patient name and demographics, or additional information such as comments, before you cycle the sample. This additional information prints on the report and is stored in the database with the results.

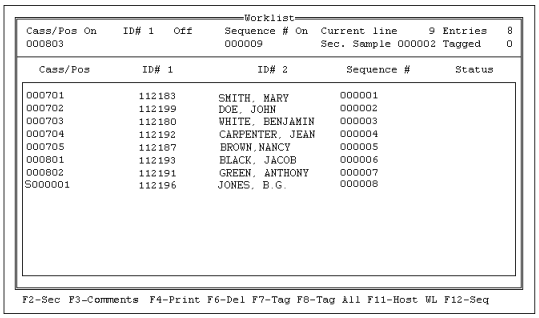
The DMS matches sample results with additional information based on Cass/Pos number and/or ID#1. You set up your choice of this primary (matching) identifier in **Screen Labels**. See Chapter 6, Sample Analysis Set Up, **Screen Labels**.

The Worklist is a list of work to be done. Once the DMS matches the results to preassigned data, the entry disappears from the Worklist.

You can preassign the Worklist manually or automatically. The procedure for manual entry is presented in this section. See Heading 3.13, Host Worklist for information about automatic preassignment.

Automatic Sequencing Set Up

To minimize typing, you can set up the Worklist to automatically sequence Cass/Pos, ID#1, Sequence #, and Secondary mode sample reference number. You set up which ones you want to automatically sequence and the starting number for each. When you preassign the Worklist, pressing Enter automatically enters the next number in the sequence.


Worklist
Cass/Pos On 000803
ID# 1 Off
Sequence # On 000009
Current line 9 Entries 8
Sec. Sample 000002 Tagged 0
Cass/Pos ID# 1 ID# 2 Sequence # Status
000701 112183 SMITH, MARY 000001
000702 112199 DOE, JOHN 000002
000703 112180 WHITE, BENJAMIN 000003
000704 112192 CARPENTER, JEAN 000004
000705 112187 BROWN,NANCY 000005
000801 112193 BLACK, JACOB 000006
000802 112191 GREEN, ANTHONY 000007
S000001 112196 JONES, B.G. 000008
F2-Sec F3-Comments F4-Print F6-Del F7-Tag F8-Tag All F11-Host WL F12-Seq

1. Access the Worklist screen:
   - at the Run Samples screen, press Ctrl + W

     OR
   - at the Access screen, press F5 **WORKLIST**

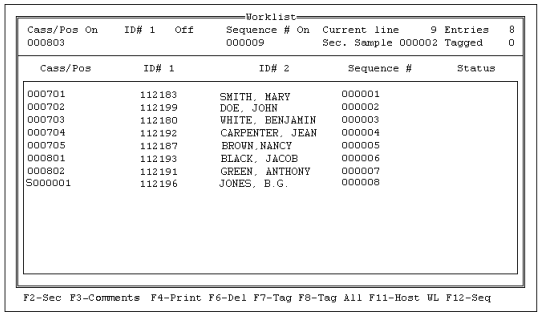
     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Worklist**.
2. Press F12 **Seq** to move the cursor to the automatic sequencing area at the top of the screen.
3. Use the Enter key to move from field to field and set up the items you want to automatically sequence.
   - Spacebar toggles between ON and OFF.
   - Type in the starting number for each item you choose to autosequence.
4. Press F12 again to move the cursor back down to the preassigning area.

Preassigning the Worklist

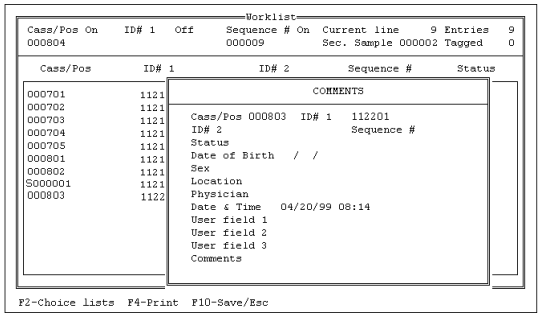
1. If not already on the Worklist screen, access it:
   - at the Run Samples screen, press Ctrl + W

     OR
   - at the Access screen, press F5 **WORKLIST**

     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Worklist**.


Worklist
Cass/Pos On ID# 1 Off Sequence # On Current line 9 Entries 8
000803 000009 Sec. Sample 000002 Tagged 0
Cass/Pos ID# 1 ID# 2 Sequence # Status
000701 112183 SMITH, MARY 000001
000702 112199 DOE, JOHN 000002
000703 112180 WHITE, BENJAMIN 000003
000704 112192 CARPENTER, JEAN 000004
000705 112187 BROWN,NANCY 000005
000801 112193 BLACK, JACOB 000006
000802 112191 GREEN, ANTHONY 000007
S000001 112196 JONES, B.G. 000008
F2-Sec F3-Comments F4-Print F6-Del F7-Tag F8-Tag All F11-Host WL F12-Seq

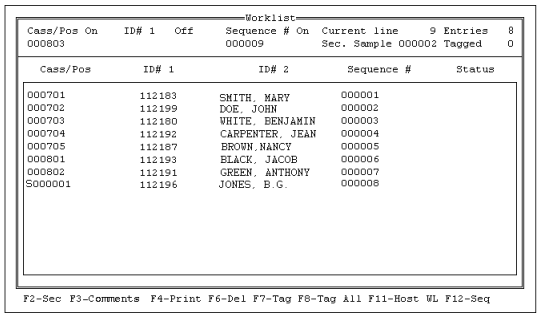
2. Will this sample be run in the Primary mode?
   - If yes, go to step 3.
   - If no, press F2 **Sec**. A Secondary mode sample reference number appears in the Cass/Pos column.
3. Enter the Cass/Pos number and/or ID#1, depending on your workflow.
   - If automatically sequencing, press Enter.
   - If not, type the Cass/Pos number and/or ID#1. Press Enter to go from one field to another.
4. Type in the sample's ID#2 and press Enter.
5. Do you want to add demographics and/or comments?
   - If no, go to step 6.
   - If yes, continue with this step.
     a) Press F3 **Comments**.
     b) Type in demographic data and comments then press F10 **Save/Esc.**



Note: Use F2 **Choice list** to choose from previously set up Location and Physician lists. To set up these lists, refer to Chapter 6, Set Up.

Note: If the Date of Birth is prior to 1990, enter all four digits of the year.

6. Enter Sequence # (optional).
   - If automatically sequencing, press Enter.
   - If not, type the sequence # or leave blank and press Enter.
7. Repeat steps 2 through 6 for each sample.
8. If you want to print the Worklist:
   a. Press F8 **Tag All**.
   b. Press F4 **Print**.
9. Press Ctrl+W to go to the Run Samples screen and cycle the specimens. They can be cycled in any order.



Status Messages

The Status column on the Worklist corresponds to the Status field on the Run Samples screen. There are two conditions that cause a sample to remain on the Worklist after it has been run. The two status messages associated with these conditions are explained below.

NO MATCH

This message means that the Cass/Pos or the ID#1 of the cycled sample did not match any of the entries on the Worklist. The most common cause is a typing error. Cycling a sample that has not been preassigned on the Worklist will also cause a *NO MATCH* unless the Worklist is completely empty.

If there are three consecutive *NO MATCH* errors:

- The system stops.
- A beeping alarm sounds.
- The error message *3 CONSECUTIVE NO MATCHES* appears at the bottom of the screen.
- The background of the WL indicator on the status line turns red.

Operator response:

1. Press Alt + End to stop the alarm.
2. Press Ctrl + W to go to the Worklist.
3. Determine the cause of the *NO MATCH* errors and take appropriate action.
4. Tag and delete some or all of the samples with *NO MATCH* errors.
   a. Use F7 to tag individual samples or F8 to tag all.
   b. Use F6 to delete them.
5. Rerun samples as necessary.

NO READ

A NO READ error message occurs only when ID#1 is the primary identifier and the bar code on the sample tube is not read. In this case, there is no way to match the results to an entry on the Worklist.

If there are three consecutive *NO READ* errors:

- The system stops.
- A beeping alarm sounds.
- The error message *3 CONSECUTIVE NO READS* appears at the bottom of the screen.
- The background of the WL indicator on the status line turns red.

Operator response:

1. Press Alt + End to stop the alarm.
2. Press Ctrl + W to go to the Worklist.
3. Determine the cause of the *NO READ* errors and take appropriate action.
4. Tag and delete some or all of the samples with *NO READ* errors.
   a. Use F7 to tag individual samples or F8 to tag all.
   b. Use F6 to delete them.
5. Rerun samples as necessary.

PART. ASP

The Worklist posts samples with aspiration errors. *PART. ASP* appears in the Status column. This happens whether or not you routinely use the Worklist.

If any combination of 10 NO READ, NO MATCH and/or PART. ASP errors accumulate on the Worklist:

- The system stops.
- A beeping alarm sounds.
- The error message *10 NO READ, NO MATCH, PART. ASP* appears at the bottom of the screen.
- The background of the WL indicator on the status line turns red.

Operator response:

1. Press Alt + End to stop the alarm.
2. Press Ctrl + W to go to the Worklist.
3. Determine the cause of the errors and take appropriate action.
4. Tag and delete some or all of the samples with errors.
   a. Use F7 to tag individual samples or F8 to tag all.
   b. Use F6 to delete them.
5. Reassign and Rerun samples as necessary.

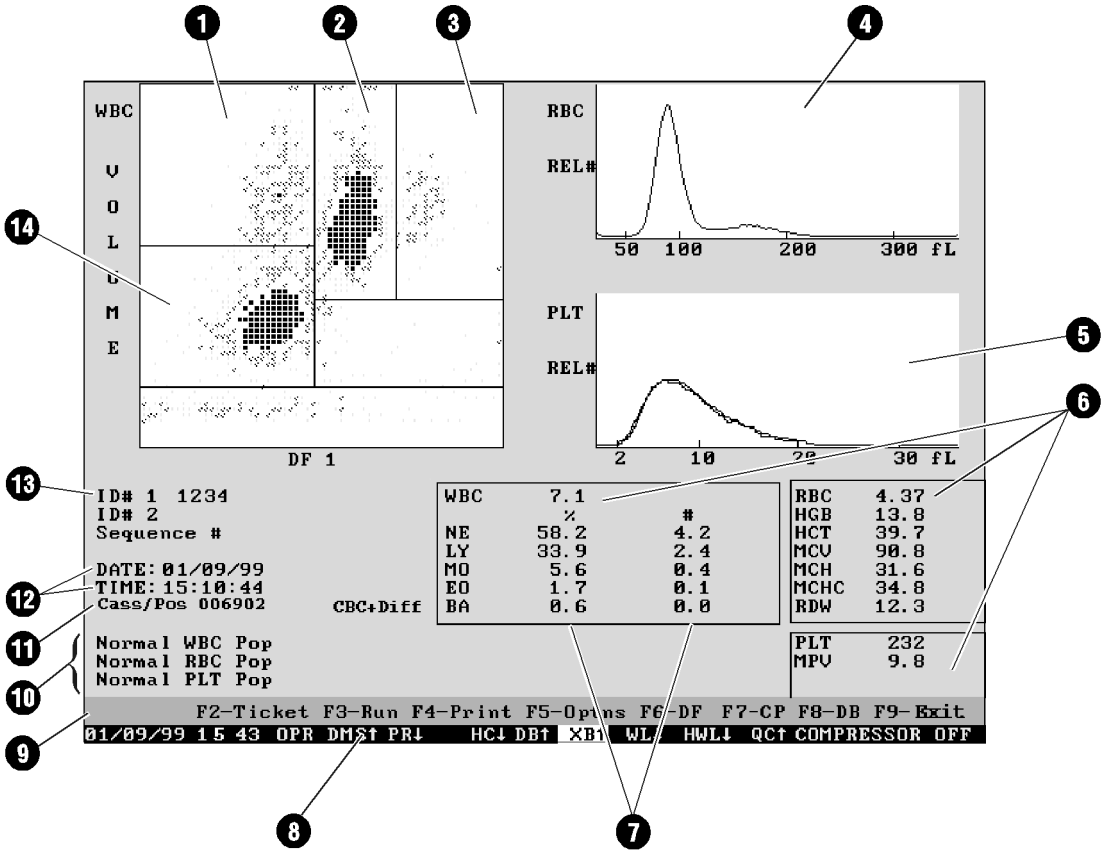
3.13 HOST WORKLIST

The Host Worklist receives sample identifiers and demographics from your host computer. The Host Worklist can hold up to 5,000 samples. Tag and transfer samples to the Worklist when you are ready to cycle them. The Worklist can accept up to 300 samples from the Host Worklist.

1. Access the Host Worklist screen:
   - at the Access screen, press F6 **HOST WORKLIST**

     OR
   - at the Main Menu, select **Sample Analysis ▸▸ Host Worklist**.
2. Use F7 to tag individual samples or F8 to tag all.
3. Press F3 to transfer tagged samples from the Host Worklist to the Worklist.

4.1 RUN SAMPLES DISPLAY

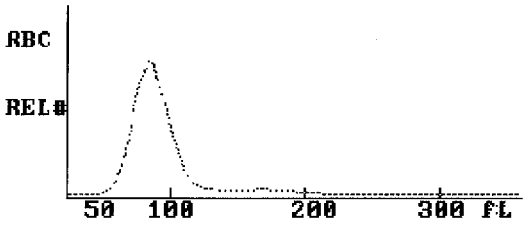


1. Monocyte Population
2. Neutrophil Population
3. Eosinophil Population
4. RBC Histogram
5. PLT Histogram
6. CBC Parameter Results
7. Diff Results
8. Status Line
9. Option (Function) Line
10. Condition Messages
11. Cass/Pos number OR
    S = Secondary PrD = Predilute RET = Retic
12. Date and Time of Analysis
13. Barcode or Keyboard Entry Identification
14. Lymphocyte and Basophil Populations

4.2 CBC HISTOGRAMS

RBC Distribution Curve

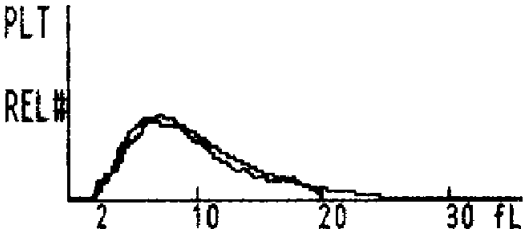
The normal RBC curve ranges from 36 to 360 fL. The display starts at 24 fL.



Plt Distribution Curve

The normal Plt distribution yields two curves, both using averaged data.

- The smooth curve derives from raw data and displays between 2 fL and 20 fL.
- The fitted curve ranges from 0 to 70 fL and is used to derive the Plt count. Only the area between 0 fL and 36 fL displays.



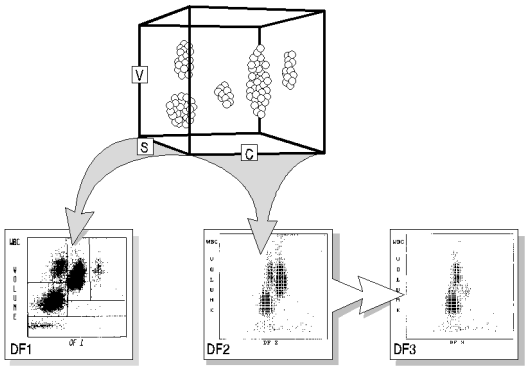
4.3 DIFF SCATTERPLOTS AND HISTOGRAMS

HmX PAK reagents maintain white cells in their near-native state.

The instrument looks at cells in all three dimensions.

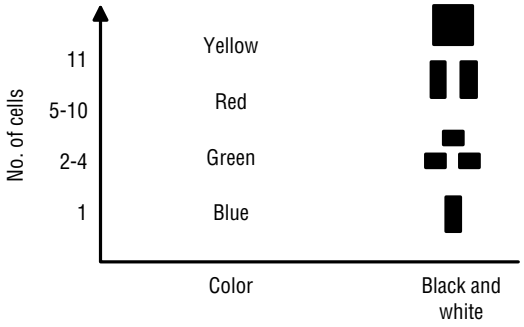
You see results on your screen

- two dimensions at a time
- in three different views.



Density

- In black and white
  highest density = blackest areas
- In color
  highest density = yellow



DF1

DF1 is always the initial display.

The horizontal spread derives primarily from light scatter.

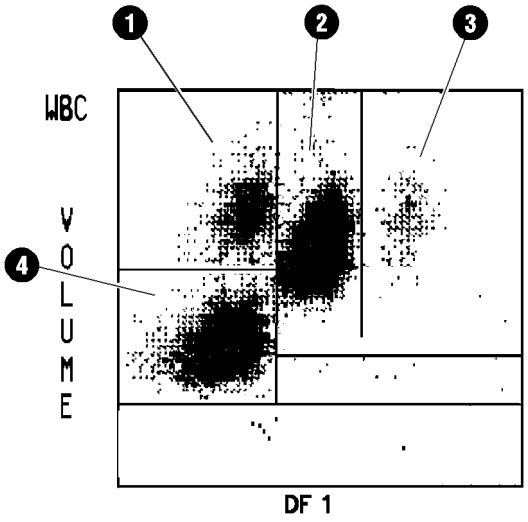
You cannot see the basophils as a separate population in this view. They are behind the upper right quadrant of the lymphocytes.

❶ Monocyte Population

❷ Neutrophil Population

❸ Eosinophil Population

❹ Lymphocyte and Basophil Populations



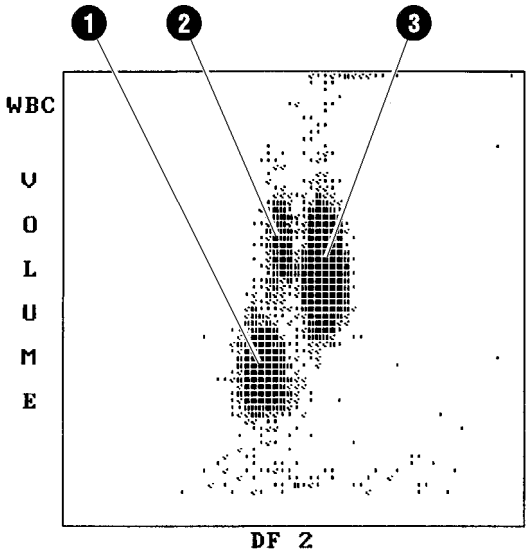
DF2

Press F6 **DF** then Alt+F2 to rotate the cube to the DF2 display. Here the horizontal spread derives primarily from conductivity.

❶ Lymphocyte Population

❷ Monocyte Population

❸ Neutrophil, Basophil, and Eosinophil Populations



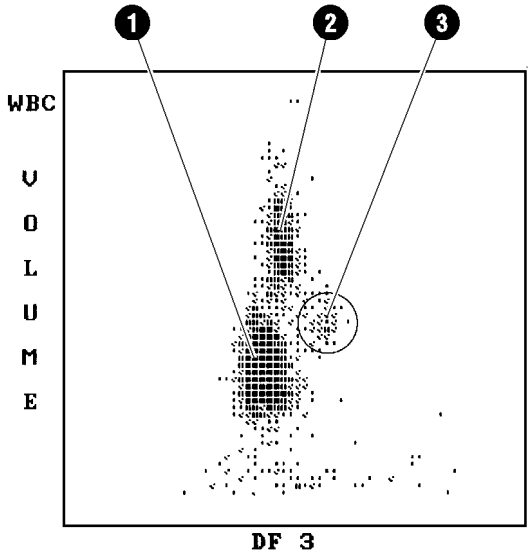
DF3

Now press Alt+F3 to display the DF3 view which shows the Neutrophils and Eosinophils gated out to reveal the Basophils.

❶ Lymphocyte Population

❷ Monocyte Population

❸ Basophil Population

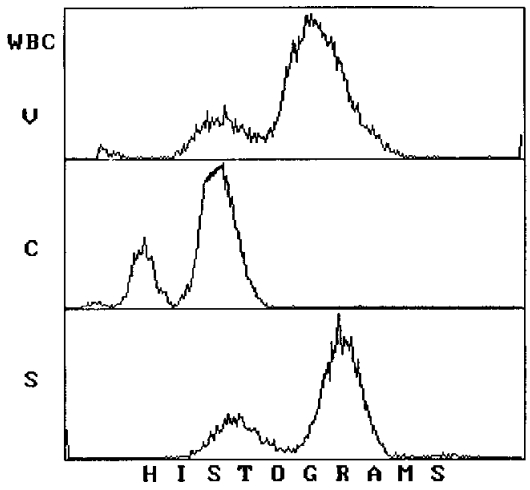


VCS Histograms

Alt+F4 displays histograms that show the distribution of

- volume
- conductivity
- scatter

across the horizontal axis.



4.4 RETICULOCYTE SCATTERPLOTS

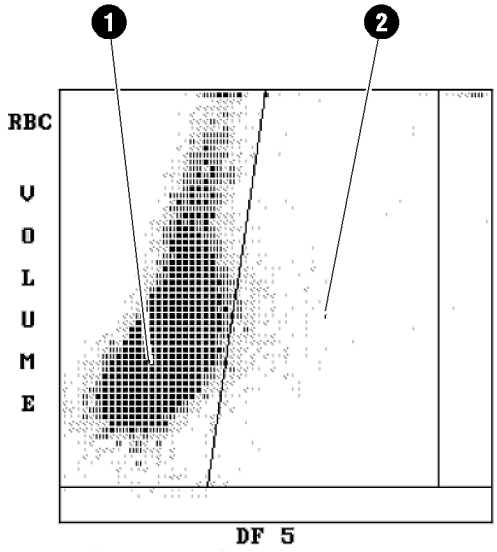
DF5

DF5 is always the initial display.

The horizontal spread displays the amount of light scatter, which is the primary counting/separating device.

❶ Mature Red Blood Cell Population

❷ Reticulocyte Population

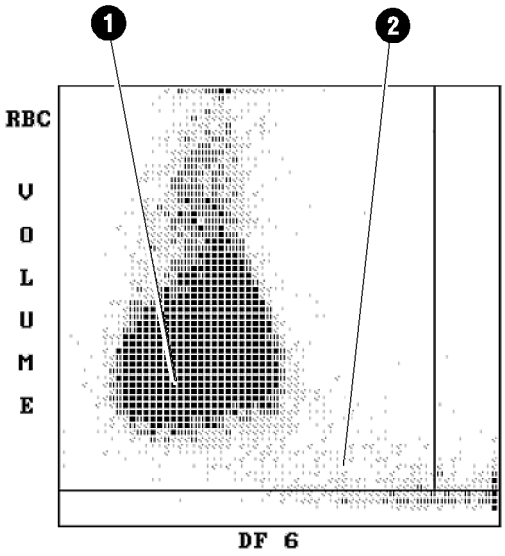


DF6

Press F6 **DF** then Alt+F2 to view DF6. The horizontal spread displays the amount of opacity, which is primarily used as a gating device to screen out all non-reticulocyte/red cell particles.

❶ Mature Red Blood Cell Population

❷ Reticulocyte Population



4.5 PARAMETER CODES

Table 4.1 lists the parameters and their codes. If any of the following flags occur, review the results for the affected parameter.

Table 4.1 Parameter Codes

On DMS Display	Cause
All Parameters	
••••• for a parameter result	Incomplete or abnormal computation.
••••• for **all** parameter results and *PART. ASP* message displayed	Sample integrity check failed.
––––– for CBC parameter results, and no average histogram for the affected parameter • If WBC is –––––, then LY#, MO#, NE#, EO#, and BA# are ••••• • If RBC is –––––, then MCH, MCHC, and Hct are also –––––	Total voteout (none of the three counts agreed). **Note:** Diff parameters do not vote out.
*V	Single-count period voteout. May indicate an erroneous result due to aperture blockage.
V	Appears next to parameters derived from the parameter with the single count period voteout.
+++++ for parameter results **IMPORTANT** If the WBC, RBC, Hgb, or Plt result is +++++, the results of the next sample could be falsely increased due to carryover. Repeat any sample that follows a sample with +++++ results. **IMPORTANT** Sample dilutions may result in erroneous differential results. Do not report the differential results from a diluted sample. **IMPORTANT** The overrange value displayed in Data Base Query F3 **Edit** is not accurate enough for reporting purposes. It is only for review to help decide how much of a dilution to make. Do not report the overrange values displayed in Data Base Query F3 **Edit**.	Result exceeds: WBC 99.9 x 10^3 cells/µL RBC 9.99 x 10^6 cells/µL Plt 999. x 10^3 cells/µL If WBC is overrange an R appears next to the RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, MPV, Plt and Diff% results. Results for Diff # are dots (•••••). If RBC is overrange an R appears next to Hct, MCH and MCHC results. If Plt is overrange an R appears next to WBC, Hgb, MCH, MCHC, diff # and Pct results. Average "ballpark" values for overrange WBC, RBC or Plt are displayed in Data Base Query, F3 **Edit**, beneath the Definitive flag section. Press End to view this display. These values do not print. Use this information only as a guide to make the appropriate dilution.
?????	DMS has received questionable data.

Table 4.1 Parameter Codes *(Continued)*

On DMS Display	Cause
All Parameters	
L next to parameter result	Result is lower than the laboratory-set patient low action limit or below the assay control lower limit.
H next to parameter result	Result is higher than the laboratory-set patient high action limit or above the assay control upper limit.
Plt Parameters	
R next to Plt and MPV results	PDW > 20, mode not between 3 and 15, or non-positive curve detected, OR Plt < 20,000 OR Total voteout of fitted curve OR WBC is overrange.
RBC Parameters	
R next to RDW result	Excessive asymmetry in RBC histogram OR WBC or MCV overrange.
*R next to MCV; also R next to RBC, Hct, MCH, MCHC, RDW, Plt, and MPV	MCV < 50 fL
WBC Parameters	
*R next to WBC; also R next to Diff numbers	Check of WBC lower threshold failed.
R next to Diff percentages and numbers	Low differential count statistics. These messages occur also: Population message: ABNORMAL WBC POP Suspect message: REVIEW SLIDE
::::: for Diff results	System detected a clog in the flow cell. There are three types of clogs: FC - Full Clog PC1 - Partial Clog 1 PC2 - Partial Clog 2 Refer to the Special Procedures and Troubleshooting manual for more information.

Retic Parameter Codes

Table 4.2 lists the parameters and their codes. If any of the following flags occur, review the results for the affected parameter.

Table 4.2 Retic Parameter Codes

Results	Message in Message Box	Code Under Scatterplot	Situation
:::::	VERIFY RETIC	FC	Full Clog. Instrument performs an Autopurge.
:::::	VERIFY RETIC		Count time failure or initial count failure.
	VERIFY RETIC		Incomplete data.
RBC xx.xx E RET# .xxxx e or RET# .xxxxeH or RET# .xxxxeL	EDITED DATA		Results entered by the operator. Calculated result. Calculated result exceeds limit of display.
RET% xx.xx +	VERIFY RETIC		RET% > 30.0% Overrange.
RET% xx.xx R	VERIFY RETIC		RET% < 0.5%
RET% xx.xx		FD	Flow deviation (underrange). Instrument performs an Auto purge. It may occur with another condition.
RET% xx.xx L or xx.xx H	VERIFY RETIC		Results < or > Action Limits.
RET% ?????	VERIFY RETIC		Invalid data: RET% < 0.00 or > 100.00.
RET# +++++	EDITED DATA		Exceeds limit of display for parameter RET# > 9.999.

4.6 MESSAGES

IMPORTANT Your HmX Hematology Analyzer with Autoloader provides you with various data, flags and graphical representations that are designed for use as an integrated report. To assure that your system provides you with the most meaningful and accurate results, set up all definitive limits according to your laboratory's established reference ranges and use all report outputs for decision-making purposes. Setting definitive limits is essential if you use Condition messages in decision making.

Use all the flagging options (suspect, definitive, high/low, parameter codes and your laboratory's flagging criteria) to optimize the sensitivity of the instrument results. Do not single out one system message or output, such as a histogram or scatterplot, to summarize the specimen or patient's condition.

Your HmX Hematology Analyzer with Autoloader provides three types of messages:

- Condition messages describe the sample's condition (normal or abnormal population).
- Definitive messages indicate that the result exceeds user-defined limits.
- Suspect messages indicate some abnormalities that exhibit the specified characteristic cluster patterns. The system generates these messages with an internal algorithm; they do not require limits.

Note the following circumstances:

1. An overrange (+++++) parameter result does not generate a definitive message but does generate an abnormal population condition message.
2. With a colon (:::::) code for the differential results, if the WBC count exceeds the limits for Leukopenia or Leukocytosis, then these definitive messages appear and an abnormal population condition message occurs.
3. If a Pancytopenia message appears, it replaces Anemia, Leukopenia and Thrombocytopenia definitive messages.

Table 4.3 summarizes the condition, definitive and suspect flagging messages.

Table 4.3 Summary of Flagging Messages

Parameter	Condition	Suspect	Definitive
WBC	Normal WBC Pop Abnormal WBC Pop No message Note: If you run with the Diff OFF, Leukopenia and Leukocytosis definitive messages will still generate Abnormal WBC Pop messages.	Blasts Imm Grans/Bands 1 Imm Grans/Bands 2 Variant Lymphs Review Slide	Leukopenia Leukocytosis Neutropenia Neutrophilia Lymphopenia Lymphocytosis Monocytosis Eosinophilia Basophilia
RBC	Normal RBC Pop Abnormal RBC Pop No message	NRBCs Dimorphic RBC Pop Micro RBCs/RBC Fragments RBC Agglutination	Anemia Anisocytosis Microcytosis Macrocytosis Hypochromia Poikilocytosis Erythrocytosis Pancytopenia
Plt	Normal Plt Pop Abnormal Plt Pop No message	Platelet Clumps Giant Platelets	Thrombocytopenia Thrombocytosis Small Platelets Large Platelets

Condition Messages

Population condition messages appear in the lower left corner of the Run Samples screen. They are:

Normal WBC Pop	*Abnormal WBC Pop*
Normal RBC Pop	*Abnormal RBC Pop*
Normal Plt Pop	*Abnormal Plt Pop*

If there is a voteout for WBC, RBC or Plt, no message appears for the respective parameter.

The system generates these population messages from one or a combination of the following: suspect messages, definitive messages or meeting the criteria of an internal algorithm that does not report a separate flag. High (H) and Low (L) flags do not cause Abnormal Pop condition messages.

When there is an abnormal population message, you can use F11 **Cell Classification** to display a window that lists the suspect and definitive messages associated with that sample. If the window does not display and the DMS instructs you to print the results to see the messages, press F4 **Print**.

Table 4.4 summarizes the origin of abnormal population messages.

Table 4.4 Origin of Abnormal Pop Messages

Message Type	Source	Characteristic
Suspect	Instrument Internal Algorithm	Some abnormalities exhibit characteristic cluster patterns that are indicated by specific suspect messages. Suspect messages alert you to the possibility of a particular abnormality. Not every atypical scatterplot has a corresponding suspect message.
Definitive	User-Defined	Messages appear at your laboratory's defined limits. If you use definitive flags or condition messages for decision-making purposes or action limits, these flags must identify the limits for review/no review, action/no action, and so on, according to your laboratory's criteria.
No Message	Instrument Internal Algorithm	Certain conditions trigger an Abnormal WBC Pop message in the absence of suspect or definitive flags.

Suspect Messages

Suspect messages flag an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. These messages appear on the sample report printout. Confirm any abnormality by microscopic review. See Table 4.3.

Definitive Messages

Set definitive flags at "decision limits" to trigger Abnormal Pop condition messages to appear when results exceed your laboratory's defined limits (low and high). Use definitive flags to denote moderate to seriously abnormal distributions. See Chapter 6, Set Up for instructions on setting limits. It is essential to set these limits if you use condition messages (Abnormal Pop) in decision making. The values you select affect when your condition messages appear.

Table 4.5 lists the limits which, if exceeded, generate the definitive flags. Results that generate these messages may require review according to your laboratory's reference range for that particular condition. See also Table 4.3.

Table 4.5 Definitive Flagging Limits

For this Parameter	This Message	Indicates the Result Exceeds this Limit
WBC	Leukopenia	Low limit for WBC
	Leukocytosis	High limit for WBC
	Neutropenia%	Low limit for NE%
	Neutrophilia%	High limit for NE%
	Lymphopenia%	Low limit for LY%
	Lymphocytosis%	High limit for LY%
	Monocytosis%	High limit for MO%
	Eosinophilia%	High limit for EO%
	Basophilia%	High limit for BA%
	Neutropenia#	Low limit for NE#
	Neutrophilia#	High limit for NE#
	Lymphopenia#	Low limit for LY#
	Lymphocytosis#	High limit for LY#
	Monocytosis#	High limit for MO#
	Eosinophilia#	High limit for EO#
	Basophilia#	High limit for BA#
RBC	Anemia	Low limit for RBC or for Hgb
	1+ Anisocytosis	High limit for RDW
	2+ Anisocytosis	A gradient range from 1+ Anisocytosis
	3+ Anisocytosis	A gradient range from 2+ Anisocytosis
	1+ Microcytosis	Low limit for MCV
	2+ Microcytosis	A gradient range from 1+ Microcytosis
	3+ Microcytosis	A gradient range from 2+ Microcytosis
	1+ Macrocytosis	High limit for MCV
	2+ Macrocytosis	A gradient range from 1+ Macrocytosis
	3+ Macrocytosis	A gradient range from 2+ Macrocytosis

Table 4.5 Definitive Flagging Limits *(Continued)*

For this Parameter	This Message	Indicates the Result Exceeds this Limit
RBC	1+ Hypochromia	Low limit for MCH
	2+ Hypochromia	A gradient range from 1+ Hypochromia
	3+ Hypochromia	A gradient range from 2+ Hypochromia
	1+ Poikilocytosis	High limit for RDW and Low limit for MCH
	2+ Poikilocytosis	A gradient range from 1+ Poikilocytosis
	3+ Poikilocytosis	A gradient range from 2+ Poikilocytosis
	Erythrocytosis	High limit for RBC
	Pancytopenia	Low limit for WBC **and** RBC **and** Plt
Plt	Thrombocytopenia	Low limit for Plt
	Thrombocytosis	High limit for Plt
	Small Platelets	Low limit for MPV
	Large Platelets	High limit for MPV

4.7 MICROSCOPIC REVIEW

If a possible abnormality appears on the report, check the blood film.

If the blood film does not appear consistent with the printed results, check for:

- Possible printer or instrument problem.
- Sample, film or report misidentification.
- Sample conditions (age, storage, anticoagulant, chemical composition, abnormally small WBCs, clumped platelets).
- Limitations of slide preparation, staining and microscopic review.
- Interfering substances (medications, cryoglobulins or cryofibrinogen crystals).
- Patient conditions (fragmented WBCs, giant platelets, platelet satellites, lyse resistant RBCs, nucleated RBCs).

4.8 DATA BASE QUERY

To access the Data Base Query screen:

- at the Access screen, press F4 **DATA BASE QUERY**

  OR

- at the Main Menu, select **Sample Analysis ▸▸ Data Base Query**.

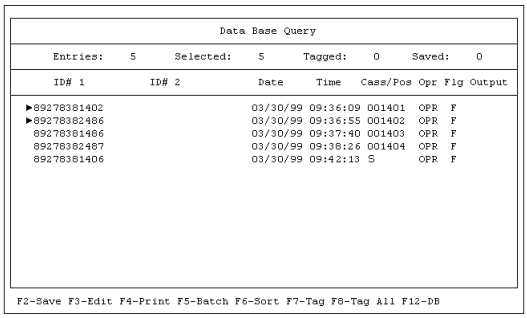
Overview

You can sort, retrieve, review, print, transmit, archive to diskette and mark for saving sample results you previously stored.

The data base stores results of up to 5,000 samples. Sample 5,001 overwrites the oldest sample not marked for saving.

Data Base Function

When you access this option, you see what was selected by the last Sort criteria. To review other samples, change the Sort criteria. If the last sorting process resulted in no entries displayed here, then when you access this option, the sort window appears.

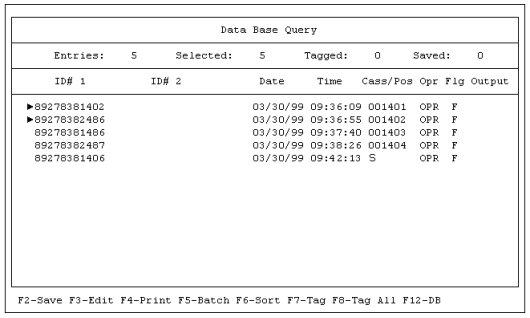


The top of the screen shows you, from left to right:

- How many entries there are in the data base
- How many entries have been selected for sorting
- How many entries are tagged for batch processing
- How many entries are marked to save at wraparound

Each data line has fields for the following information about a sample:

- A pointer character if the sample is tagged
- ID #1
- The secondary identifier (ID #2), if one has been entered, for example, a name.
- Date and time of cycle
- Cass/Pos field
  - Cass/Pos number = Primary mode
  - S = Secondary mode
  - PrD = Predilute CBC mode
  - RET = Retic mode
- The operator identification (Opr) at time of cycle
- Flags field (Flg):
  - Blank means not flagged
  - F means flagged
  - PA means Partial Aspiration
- Output field:
  - P = Batch Print
  - H = Host
  - S = Save
  - A = Archive



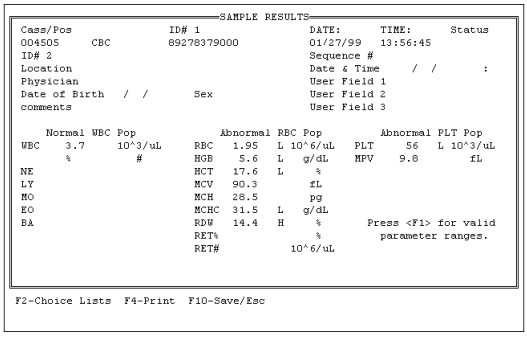
Screen-Specific Function Keys

F2 Save
Marks a sample to save it from overwriting. Place the cursor on the sample to be saved and press this key. You can save 150 samples.

F3 Edit
Displays the highlighted sample data. Press End to display the average values for overrange results. These values appear as +++++ for parameter results on the Run Samples screen.

Note: The overrange values are provided for review only; do not report them. For more information refer to table 4.1, Parameter Codes.

After you press F3 **Edit**, the Sample Results screen appears. The function key options on this screen are:



F2 Choice Lists

When you move the cursor to the field, displays location or physician's choice list.

F4 Print

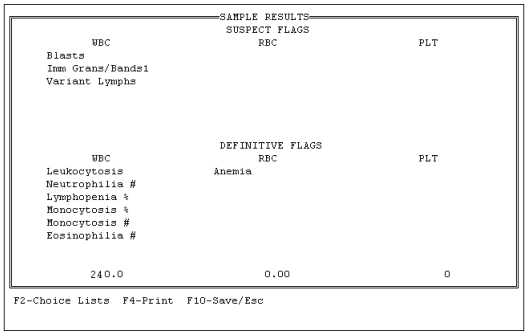
Prints the screen.

F10 Save/Esc

Saves and escapes to the previous screen

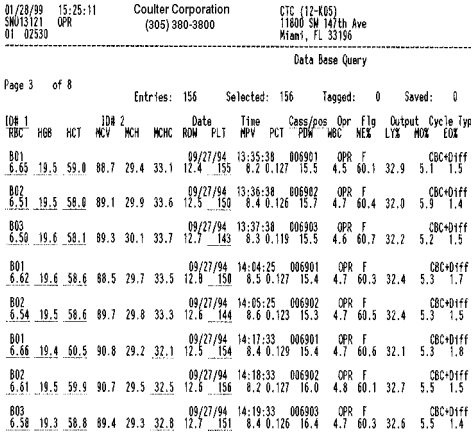
End

Shows Suspect and Definitive Flags screen and overrange results if any.

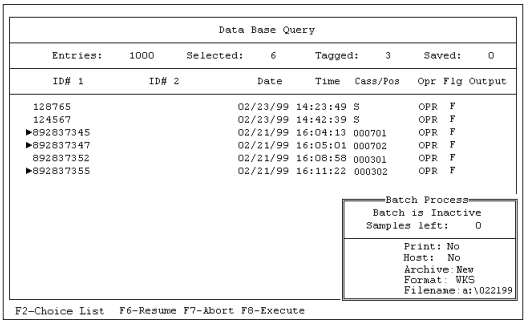


F4 Print

Generates the line list printout of all the sorted samples. Underlining of parameter data indicates that it was flagged.



F5 Batch


Data Base Query
Entries: 1000 Selected: 6 Tagged: 3 Saved: 0
ID# 1 ID# 2 Date Time Cass/Pos Opr Flg Output
128765 02/23/99 14:23:49 S OPR F
124567 02/23/99 14:42:39 S OPR F
▶892837345 02/21/99 16:04:13 000701 OPR F
▶892837347 02/21/99 16:05:01 000702 OPR F
892837352 02/21/99 16:08:58 000301 OPR F
▶892837355 02/21/99 16:11:22 000302 OPR F
Batch Process
Batch is Inactive
Samples left: 0
Print: No
Host: No
Archive: New
Format: WKS
Filename: a:\022199
F2-Choice List F6-Resume F7-Abort F8-Execute

- Print tagged results in graphic format
- Transmit tagged results to the host computer or
- Archive tagged results to diskette.

More information on each of these features is presented later in this section.

When the **F5 Batch** window is displayed, you have these function keys:

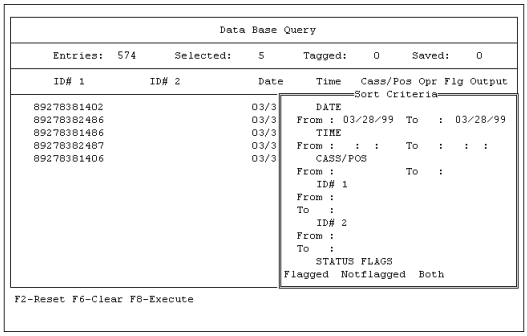
F2 Choice List
Available only when the Archive field is highlighted. Choose between No, New, and All.

F6 Resume
Resumes batch processing.

F7 Abort
Ends batch processing.

F8 Execute
Starts the batch processing.
SELECT FUNCTION must be displayed on the status line.

Sorting



F6 Sort

Displays the sort criteria window. Select the group of samples you want to review.

The maximum number of samples that can be selected for sort is 1,000. If you have more samples than 1,000 to be sorted, you must restart the sort after the last selected sample.

Sort Rules

1. You can sort by either ID#1 or ID#2, but not both at the same time.
2. If you sort by numeric ID, make all numbers the same length (use leading zeros if necessary).
3. Time requires entry of date, hour, minute and seconds.
4. Use the correct (upper or lower) case when sorting with alphanumeric characters.
5. You can sort by cassette and position.
6. Select results F (Flagged), N (Non-flagged) or B (Both). Non-flagged samples are sorted and listed first.
7. If you do not choose any sort criteria, the samples in the data base are sorted chronologically by date and time.

Screen-Specific Function Keys:

F2 Reset

Restores the sort criteria set up to the last time you sorted the data.

F6 Clear

Erases the sort criteria the cursor is on.

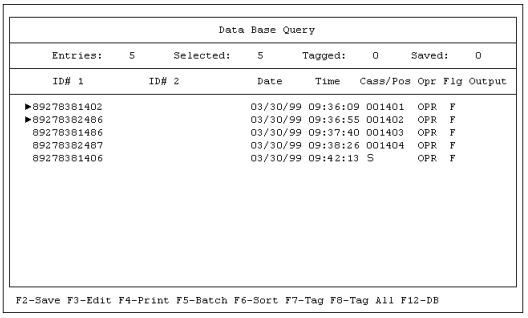
F8 Execute

Executes the sorting process after all sort criteria are entered. The samples matching the sort criteria are displayed on the screen.

F7 Tag
Tags or untags a highlighted sample for batch processing.

F8 Tag All
Tags or untags all samples for batch processing.

F12 DB
Displays the sample result graphics screen of the highlighted sample on the Run Samples Database screen. You can look at other sample DB results, from the same sort, without leaving this screen.



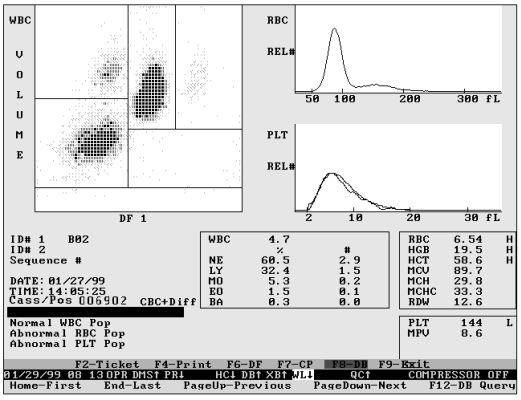
Home
Displays first sample of the sort.

End
Displays last sample of the sort.

Page Up
Displays the previous sample.

Page Down
Displays next sample.

F12
Returns to Data Base Query screen.



Editing

Edit samples in the data base with this option. If a field is edited, an E appears in the field in:

- Sample Analysis displays
- Data Base displays
- Transmission to host
- Printouts.

E overrides an H/L flag and appears in the same position.

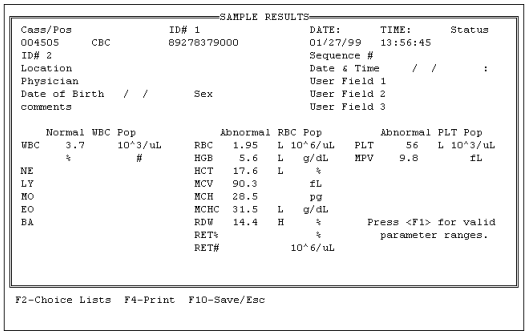
You can edit parameter results of +++++, – – – – – or ::::: . If you edit a result, an E appears next to it. The system backlights edited non-cycled parameter labels.

Do Not Edit

1. You cannot edit samples with a *NO READ*, *NO MATCH* or *PART. ASP* message in the Status field.
2. You cannot edit the primary identifier, sequence number, or the date and time the sample was processed.
3. Do not edit values that have dependent parameters without also changing the dependent parameters. For example, you must change diff absolute numbers to reflect a change in the WBC.

Edit a Sample

1. Select **Sample Analysis ▸▸ Data Base Query.**
2. Perform a sort that includes the sample you want to edit.
3. Highlight the patient sample to edit.
4. Press F3 **Edit** to go to the Sample Results screen.


SAMPLE RESULTS
Cass/Pos ID# 1 DATE: TIME: Status
004505 CBC 89278379000 01/27/99 13:56:45
ID# 2 Sequence #
Location Date & Time / / :
Physician User Field 1
Date of Birth / / Sex User Field 2
comments User Field 3
Normal WBC Pop Abnormal RBC Pop Abnormal PLT Pop
WBC 3.7 10^3/uL RBC 1.95 L 10^6/uL PLT 56 L 10^3/uL
% # HGB 5.6 L g/dL MPV 9.8 fL
NE HCT 17.6 L %
LY MCV 90.3 fL
MO MCH 28.5 pg
EO MCHC 31.5 L g/dL
BA RDW 14.4 H % Press <F1> for valid
RET% % parameter ranges.
RET# 10^6/uL
F2-Choice Lists F4-Print F10-Save/Esc

5. Move to fields that need to be edited with ↑ ↓ ← and → keys.

   Highlight the field and type the new data. If the date of birth is prior to 1990, enter all four digits of the year.
6. An E appears in all edited results fields.
7. When you edit a non-cycled parameter, the system backlights the result field. When you edit either the RBC result or RET% result, the system computes RET# and displays an e next to RET#, indicating that it is computed using an edited parameter. The system also displays an H or L if RET# is higher or lower than the defined limits.
8. Press F10 **Save/Esc**.

Results of Changed Parameters

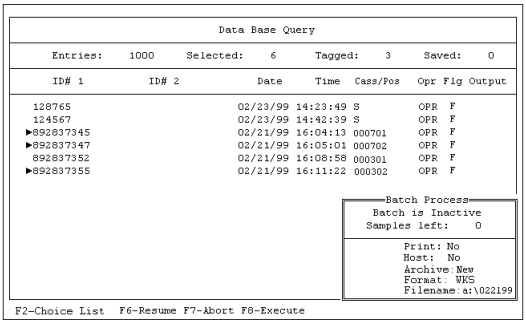
If you change any parameter result:

- All population Suspect and Definitive messages are deleted from the data base.
- The message EDITED DATA appears in the Population message field.
- No Population Suspect or Definitive messages are printed or transmitted to a host computer.
- The EDITED DATA message appears on all printouts.
- An E and/or e appears on all printouts next to the edited result.
- Data transmitted to a host computer includes the EDITED DATA message and the E/e flags.

Batch Processing

You can batch print in graphics format, batch transmit to a host computer, or archive a batch of sample results to a diskette. Perform only one batch process at a time.

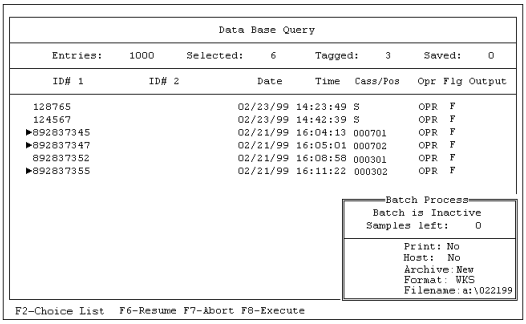
Batch Print


Data Base Query
Entries: 1000 Selected: 6 Tagged: 3 Saved: 0
ID# 1 ID# 2 Date Time Cass/Pos Opr Flg Output
128765 02/23/99 14:23:49 S OPR F
124567 02/23/99 14:42:39 S OPR F
▶892837345 02/21/99 16:04:13 000701 OPR F
▶892837347 02/21/99 16:05:01 000702 OPR F
892837352 02/21/99 16:08:58 000301 OPR F
▶892837355 02/21/99 16:11:22 000302 OPR F
Batch Process
Batch is Inactive
Samples left: 0
Print: No
Host: No
Archive: New
Format: WKS
Filename: a:\022199
F2-Choice List F6-Resume F7-Abort F8-Execute

1. Select **Sample Analysis ▸▸ Data Base Query**.
2. Perform a sort that includes the samples you want to batch print.
3. Use F7 or F8 to tag the samples you want to batch print.
4. Press F5 **Batch** to display the Batch Process window.
5. Move the cursor to the **Print:** field and use the Spacebar to toggle to YES.
6. Press F8 **Execute**.

   Note: During batch printing, PR↑ changes to BA↑, and then to PR↑.

Batch Transmit

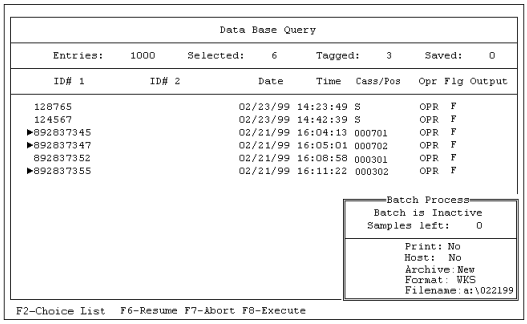

Data Base Query
Entries: 1000 Selected: 6 Tagged: 3 Saved: 0
ID# 1 ID# 2 Date Time Cass/Pos Opr Flg Output
128765 02/23/99 14:23:49 S OPR F
124567 02/23/99 14:42:39 S OPR F
▶892837345 02/21/99 16:04:13 000701 OPR F
▶892837347 02/21/99 16:05:01 000702 OPR F
892837352 02/21/99 16:08:58 000301 OPR F
▶892837355 02/21/99 16:11:22 000302 OPR F
Batch Process
Batch is Inactive
Samples left: 0
Print: No
Host: No
Archive: New
Format: WKS
Filename: a:\022199
F2-Choice List F6-Resume F7-Abort F8-Execute

1. Select **Sample Analysis ▸▸ Data Base Query**.
2. Perform a sort that includes the samples you want to batch transmit.
3. Use F7 or F8 to tag the samples you want to batch transmit.
4. Press F5 **Batch** to display the Batch Process window.
5. Move the cursor to the **Host:** field and use the Spacebar to toggle to YES.
6. Press F8 **Execute**.

Archive

The DMS Archive feature lets you copy patient result data from the DMS onto a diskette and retrieve it on another computer in a spreadsheet format. Use a spreadsheet program that is compatible with the WKS format.

To Archive


Data Base Query
Entries: 1000 Selected: 6 Tagged: 3 Saved: 0
ID# 1 ID# 2 Date Time Cass/Pos Opr Flg Output
128765 02/23/99 14:23:49 S OPR F
124567 02/23/99 14:42:39 S OPR F
▶892837345 02/21/99 16:04:13 000701 OPR F
▶892837347 02/21/99 16:05:01 000702 OPR F
892837352 02/21/99 16:08:58 000301 OPR F
▶892837355 02/21/99 16:11:22 000302 OPR F
Batch Process
Batch is Inactive
Samples left: 0
Print: No
Host: No
Archive: New
Format: WKS
Filename: a:\022199
F2-Choice List F6-Resume F7-Abort F8-Execute

1. Select **Sample Analysis ▸▸ Data Base Query**.
2. Perform a sort that includes the samples you want to archive.
3. Use F7 or F8 to tag the samples you want to archive.
4. Press F5 **Batch** to display the Batch Process window.
5. Move the cursor to the Archive field then press F2 **Choice List**.
6. Use the Spacebar to highlight your choice then press Enter.
   - If you select New, all tagged samples that have not yet been archived will be processed.
   - If you select All, all tagged samples will be processed, even if they have already been archived.
   - If you select No, Archive is inactive.
7. Move the cursor to the Filename: field and enter a file name of your choice. Type **A:** then up to eight characters. An extension is not required.

   Example: **A:\022199** could be the file name for sample results archived on February 21, 1999.
8. Insert a formatted diskette into the DMS diskette drive.
9. Press F8 **Execute**.

IMPORTANT Do not remove the diskette from the drive until the *Batch is Inactive* message appears in the Batch Process window. Removing the disk sooner can cause disk corruption.

10. Wait until the *Batch is Inactive* message appears, then remove the diskette from the diskette drive.

Note: If the space on the diskette is insufficient for archiving all of the tagged samples, the DMS displays the error *DISK FULL - ARCHIVING DISCONTINUED*. Remove the full disketted from the DMS diskette drive and insert an empty formatted diskette. Ensure the Archive option selected is **New** then press F8 **Execute**. Any samples tagged but not archived yet are copied onto the new diskette.

To Review Archived Files

1. Insert the diskette into a computer with a spreadsheet program that is compatible with the WKS format.
2. Retrieve the file you want.

Each column is labeled, but some of the labels are condensed. To view the complete column label either

- widen the column, or
- move the active cell cursor to the label.

Some of the columns use one-character codes to represent what is in them. The key to these codes is as follows:

- In the C/P Edit and ID1 Edit fields:
  - 0 = not edited
  - 1 = edited
- In the Status field:
  - 0 = Blank/Not used/Matched
  - 1 = Partial aspiration
  - 2 = No Match
  - 3 = No Read
- For WBC/RBC/Plt Population:
  - 0 = Normal
  - 1 = Abnormal
  - 2 = Edited
- For all Suspect and Definitive flags except Imm Grans/Bands:
  - blank = no flag
  - 1 = flag
- For the Imm Grans/Bands Suspect flag:
  - blank = no flag
  - 1 = IMM GRANS/BANDS 1
  - 2 = IMM GRANS/BANDS 2
- In the Mode of Aspiration field:
  - 1 = Primary mode
  - 2 = Secondary mode

4.9 WORKLOAD RECORDING

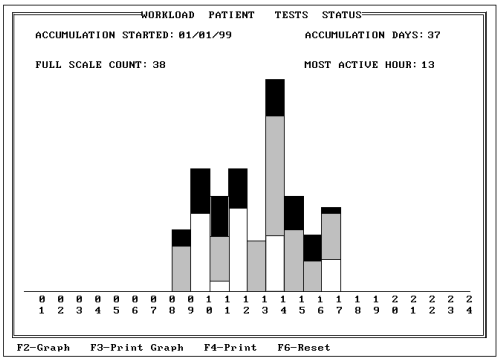
To access Workload Recording, select **Special Functions ▸▸ Diagnostics ▸▸ Workload Recording**.

The Workload Recording feature keeps a log of all samples cycled and separates patient tests from non-patient tests. Data is presented in tabular form and as a bar graph. Each test is color-coded on the bar graph.

Patient Tests Bar Graph

In the Patient Test Status mode, the colors and their designations are:

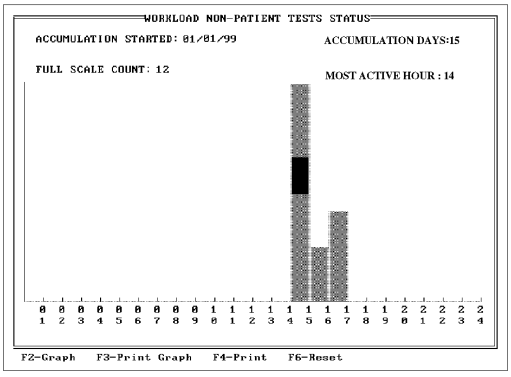
- Dark magenta - Primary mode, CBC
- Light magenta - Secondary mode, CBC
- Dark blue - Primary mode, CBC and differential
- Light blue - Secondary mode, CBC and differential



Non-Patient Tests Bar Graph

In the Non-Patient Test Status mode, the colors and their designations are:

- Dark green - CBC and CBC+Diff Control
- Light green - LATRON
- White - Calibration
- Red - Other tests



5.1 SHUT DOWN

Shut down your HmX Hematology Analyzer with Autoloader for at least 30 minutes each day it is in use.

1. Make sure the status line displays SELECT FUNCTION.
2. Select **Diluter Functions ▸▸ Shut Down.**
3. Press Enter to begin.

Allow cleaning agent to remain in the instrument for a minimum of 30 minutes.

Perform Start Up before running samples or controls.

5.2 CLEAN CYCLE

The Clean Cycle consists of a Shut Down cycle followed 30 minutes later by a Start Up cycle.

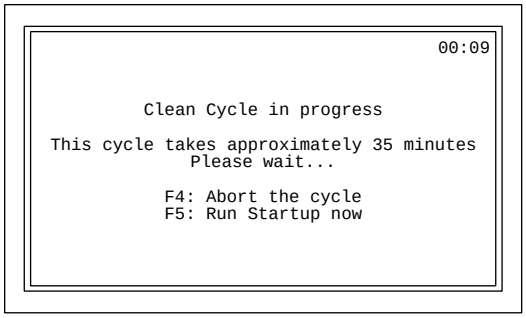
To initiate the Clean Cycle:

1. Go to the Access screen (F1 from the Main Menu).
2. Press F3 **CLEAN**.
3. Press Enter to begin.

After the Shut Down portion of the cycle finishes, a window displays.

Your options are:

- Do nothing and allow the Clean Cycle to complete.
- Press F4 to abort the Clean Cycle. Cleaning agent remains in the system until you perform Start Up.
- Press F5 to begin the Start Up cycle immediately.



5.3 PROLONGED SHUTDOWN PROCEDURE

If you turn off the power at night and the instrument is going to be idle for more than 48 hours, perform the following procedure.

1. Go to the Access screen and press F3 **CLEAN**.
2. Once the cycle is complete, turn OFF the instrument using the On/Off switch on the back of the main unit.
3. When it is time to use the instrument
   a. Turn power ON
   b. Prime the HmX PAK
   c. Perform Start Up.
4. Perform and verify QC checks according to your laboratory's protocol.
5. Operate as usual.

5.4 AUTOPURGE CYCLE

WARNING To prevent injury, turn the power OFF when performing any manual cleaning, replacement or adjustment procedures if the instrument has been in Shut Down more than 22 hours. The Autopurge cycle turns on the pneumatics power supply and performs a special Diluter cycle automatically 23 hours after a Shut Down cycle has been initiated. This cycle repeats every 24 hours after that.

After 23 hours in Shut Down, with the power ON and the pneumatics OFF, the system automatically:

- Turns ON the pneumatics.
- Purges the flow cell and sample lines with diluent.
- Turns OFF the pneumatics.
- Repeats this cycle every 24 hours until a Start Up is performed.

6.1 CHAPTER OVERVIEW

This chapter presents all of the options available in the Set Up area of the DMS software.

In Heading 6.2, Control Set Up, you will find information about:

- CBC/DIFF file
- Latex file
- CBC file
- RETIC file
- Auto-Stop

In Heading 6.3, Sample Analysis Set Up, you will find information about:

- Action limits
  - XB limits
  - Definitive flag limits
  - High/low flag limits
  - Laboratory Normal Ranges
- Location list
- Physician list
- Display formats
  - Screen Labels
  - Parameter Selection
  - Reporting Units
- Delete database
- Delete host spooler
- Clear printer spooler queue
- Print options
  - Auto Print Format
  - Ticket Options
  - Spooler Priority
  - Graphics Options
  - Optional Printer

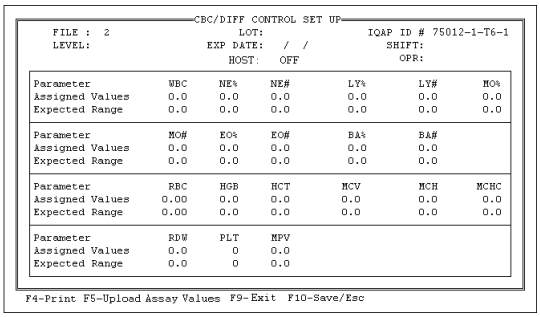
In Heading 6.4, System Set Up, you will find information about:

- Shift
- Reagents
- Institution
- Communication def
  - Host Computer Definition
- IQAP ID#
- Set Date/Time
- Supervisor Password
- Optimize Hard Disk

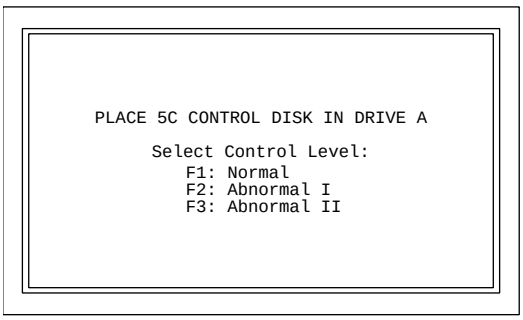
6.2 CONTROL SET UP

CBC/DIFF file

1. Select **Special Functions ▸▸ Set Up ▸▸ Control set up ▸▸ CBC/DIFF file**.
2. Select a file to set up.
3. Insert the 5C cell control diskette into the diskette drive of the computer.
4. Press F5 **Upload Assay Values**.


CBC/DIFF CONTROL SET UP
FILE : 2
LEVEL:
LOT:
EXP DATE: / /
HOST: OFF
IQAP ID # 75012-1-T6-1
SHIFT:
OPR:
Parameter WBC NE% NE# LY% LY# MO%
Assigned Values 0.0 0.0 0.0 0.0 0.0 0.0
Expected Range 0.0 0.0 0.0 0.0 0.0 0.0
Parameter MO# EO% EO# BA% BA#
Assigned Values 0.0 0.0 0.0 0.0 0.0
Expected Range 0.0 0.0 0.0 0.0 0.0
Parameter RBC HGB HCT MCV MCH MCHC
Assigned Values 0.00 0.0 0.0 0.0 0.0 0.0
Expected Range 0.00 0.0 0.0 0.0 0.0 0.0
Parameter RDW PLT MPV
Assigned Values 0.0 0 0.0
Expected Range 0.0 0 0.0
F4-Print F5-Upload Assay Values F9-Exit F10-Save/Esc

5. Press the function key for the desired level of control.
   F1 for Normal
   F2 for Abnormal I
   F3 for Abnormal II



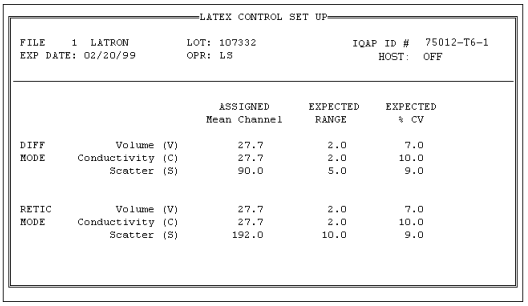
6. Manually enter Shift and Operator ID.
7. Check that HOST: is set according to your laboratory protocol. ON means that control run results are transmitted to your host computer at the time of the run. Spacebar toggles between ON and OFF.
8. Check all entries to make sure they are correct then press F10 to save and escape.
9. Repeat steps 2 through 8 for the other levels of control. Once you are finished, remove the 5C cell control diskette from the diskette drive of the computer.

If the 5C cell control diskette fails to upload, you can enter all data manually.

- Refer to the package insert for lot specific information and assigned values.
- The system automatically enters the level and expected ranges based on the first two digits of the lot number.
- Press Enter after each entry.
- Press ↓ at the end of each row of assigned values unless you are also entering your own expected ranges.

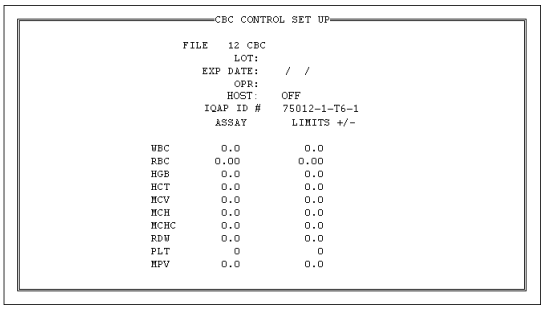
Latex file

1. Select **Special Functions ▸▸ Set Up ▸▸ Control set up ▸▸ Latex file**.
2. Select a file to set up.
3. Manually enter the name of the file, Lot #, expiration date, and Operator ID. The system automatically enters assigned values, expected ranges, and expected %CVs.
4. Check that HOST: is set according to your laboratory protocol. ON means that control run results are transmitted to your host computer at the time of the run. Spacebar toggles between ON and OFF.
5. Check all entries to make sure they are correct then press F10 to save and escape.



CBC file

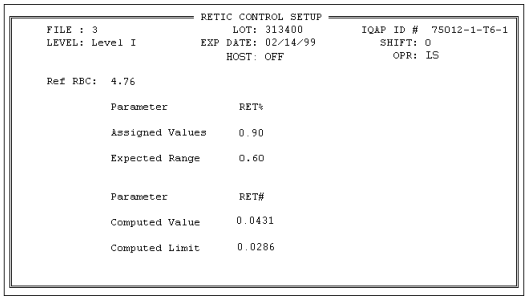
1. Select **Special Functions ▸▸ Set Up ▸▸ Control set up ▸▸ CBC file**.
2. Select a file to set up.
3. Manually enter data.
4. Check that HOST: is set according to your laboratory protocol. ON means that control run results are transmitted to your host computer at the time of the run. Spacebar toggles between ON and OFF.
5. Check all entries to make sure they are correct then press F10 to save and escape.



RETIC file

1. Select **Special Functions ▸▸ Set Up ▸▸ Control set up ▸▸ RETIC file**.
2. Select a file to set up.
3. Manually enter the data from the package insert, Shift, and Operator ID.
4. Check that HOST: is set according to your laboratory protocol. ON means that control run results are transmitted to your host computer at the time of the run. Spacebar toggles between ON and OFF.
5. Check all entries to make sure they are correct then press F10 to save and escape.

Note: If you report Retic number (RET #), it is important that you enter the correct RBC value from your assay sheet. If you enter the wrong number and then correct it after running controls, the DMS does not recalculate the incorrect RET # results.



Auto-Stop

You can set up the instrument to stop automatically if any of the errors in table 6.1 occur during a control run.

If you set Auto-Stop to ON:

The instrument stops and a beeping alarm sounds when a control error listed in Table 6.1 occurs.

Operator response:

1) Press Alt+End to stop the beeping.
2) Press Ctrl+F2 to display the Error File.
3) Take appropriate action to resume operation.

If you set Auto-Stop to OFF:

The instrument continues analyzing samples when a control error occurs.

To set Auto Stop:

1. Select **Special Functions ▸▸ Set Up ▸▸ Control set up ▸▸ Auto-Stop**
2. Press Spacebar to choose between ON and OFF.
3. Press F10 to save and escape.

Note: The arrow next to QC on the status line indicates whether the Auto Stop option is ON or OFF.

QC↑ - ON QC↓ - OFF

Table 6.1 Control Error Message Status and Action

Message	System Status	Data Status	Action
Control Out of Range	System continues or if Auto-Stop ON, stops.	Results in Control file	1. Review results. 2. Follow your laboratory's protocol.
Control Expired	System continues or if Auto-Stop ON, stops.	Results in Control file	1. Review file setup. 2. Verify Lot # & Exp. date. 3. Correct error.
File Full	System continues or if Auto-Stop ON, stops.	Bar code-labeled results lost. Results without bar-code labels saved in data base unless Control Run screen is on display. If Control Run screen is on display and no bar code read, results lost.	1. Print file, if necessary. 2. Delete file. 3. Rerun control.
File not Found (CBC/DIFF only)	System continues or if Auto-Stop ON, stops.	Bar code-labeled results lost.	1. Review file setup. 2. Correct error. 3. Rerun control.
Disk Drive C: Full	System continues or if Auto-Stop ON, stops.	Bar code-labeled results lost. Results without bar-code labels saved in data base.	Call your Beckman Coulter representative.

6.3 SAMPLE ANALYSIS SET UP

Action limits

Here you set the limits for XB, Definitive flags and High/Low flags according to your laboratory protocol. Enter your Laboratory Normal Ranges in the DMS if you want them to print on the report. Access to this area of the software requires the supervisor password.

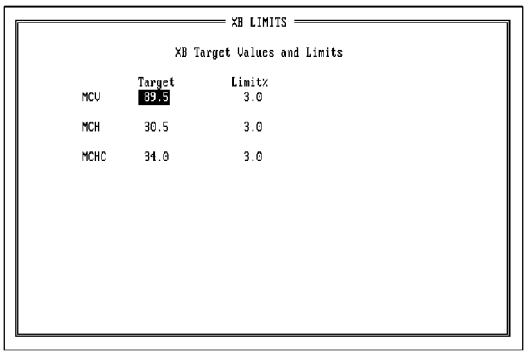
For more information on XB, refer to Chapter 2. For more information on flags, refer to chapter 4.

Note: If flagging limits are changed, flag assignments on previously stored data will not update and will not correspond to the new limits.

XB limits

Enter XB target values and thier limits here.

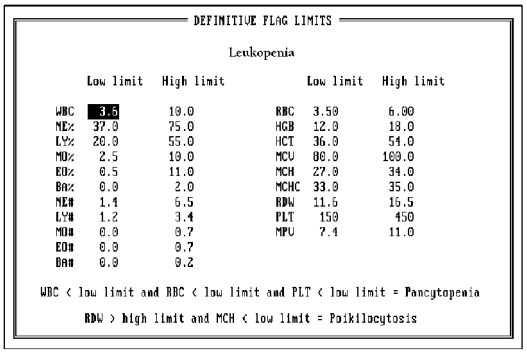
1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Action limits ▸▸ XB limits**.
2. Move the cursor to the desired field.
3. Type the data then press Enter.
4. Repeat steps 2 and 3 until all data has been entered.
5. Press F10 to save and escape.



Definitive flag limits

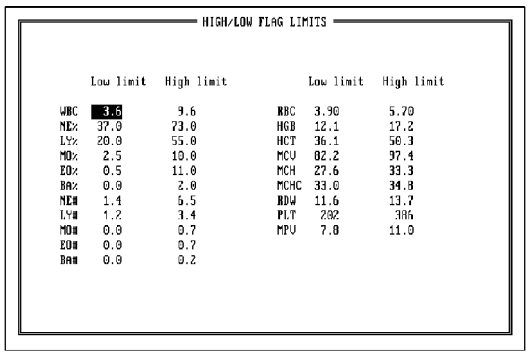
Enter your definitive flag limits here. As you highlight each limit, the flag associated with it appears at the top of the screen. If a particular limit does not have a flag associated with it, the area at the top of the screen will be blank.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Action limits ▸▸ Definitive flag limits**.
2. Move the cursor to the desired field.
3. Type the numeric limit then press Enter.
4. Repeat steps 2 and 3 until all data has been entered.
5. Press F10 to save and escape.


DEFINITIVE FLAG LIMITS
Leukopenia
Low limit
High limit
Low limit
High limit
WBC 3.5 10.0 RBC 3.50 6.00
NE% 37.0 75.0 HGB 12.0 18.0
LY% 20.0 55.0 HCT 36.0 54.0
MO% 2.5 10.0 MCV 80.0 100.0
EO% 0.5 11.0 MCH 27.0 34.0
BA% 0.0 2.0 MCHC 33.0 35.0
NE# 1.1 6.5 RDW 11.6 16.5
LY# 1.2 3.4 PLT 150 450
MO# 0.0 0.7 MPV 7.4 11.0
EO# 0.0 0.7
BA# 0.0 0.2
WBC < low limit and RBC < low limit and PLT < low limit = Pancytopenia
RDW > high limit and MCH < low limit = Poikilocytosis

High/low flag limits

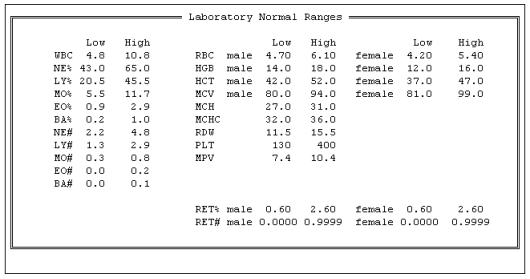
Enter High/Low flag limits here. The H or L will appear next to the numeric result that exceeds the limit.



1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Action limits ▸▸ High/low flag limits**.
2. Move the cursor to the desired field.
3. Type the numeric limit then press Enter.
4. Repeat steps 2 and 3 until all data has been entered.
5. Press F10 to save and escape.

Laboratory Normal Ranges

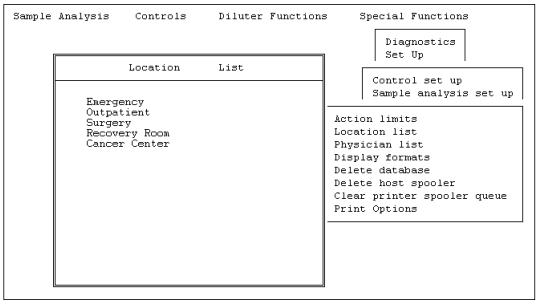
Enter your laboratory's normal ranges here. These do not trigger any flags. They serve only as a reference on printed reports.


Laboratory Normal Ranges
Low High Low High Low High
WBC 4.8 10.8 RBC male 4.70 6.10 female 4.20 5.40
NE% 43.0 65.0 HGB male 14.0 18.0 female 12.0 16.0
LY% 20.5 45.5 HCT male 42.0 52.0 female 37.0 47.0
MO% 5.5 11.7 MCV male 80.0 94.0 female 81.0 99.0
EO% 0.9 2.9 MCH 27.0 31.0
BA% 0.2 1.0 MCHC 32.0 36.0
NE# 2.2 4.8 RDW 11.5 15.5
LY# 1.3 2.9 PLT 130 400
MO# 0.3 0.8 MPV 7.4 10.4
EO# 0.0 0.2
BA# 0.0 0.1
RET% male 0.60 2.60 female 0.60 2.60
RET# male 0.0000 0.9999 female 0.0000 0.9999

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Action limits ▸▸ Laboratory Normal Ranges**.
2. Move the cursor to the desired field.
3. Type the data then press Enter.
4. Repeat steps 2 and 3 until all data has been entered.
5. Press F10 to save and escape.

Location list

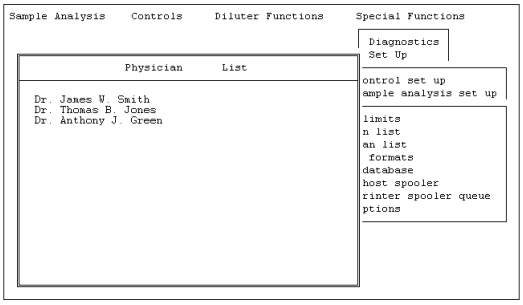
Create a list of up to 30 location names. The maximum number of characters per name is 16. Select from this list using F2 **Choice list** when entering demographic data on a Worklist or when editing data in Data Base Query.



1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Location list**.
2. Type a location name then press Enter.
3. Repeat step 2 until all locations have been entered.
4. Press F10 to save and escape.

Physician list

Create a list of up to 30 physician names. The maximum number of characters per name is 22. Select from this list using F2 **Choice list** when entering demographic data on a Worklist or when editing data in Data Base Query.



1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Physician list**.
2. Type a physician name then press Enter.
3. Repeat step 2 until all physicians have been entered.
4. Press F10 to save and escape.

Display formats

Here you set up your laboratory's choice of format for screen labels, select which parameters to display and select the reporting units you are going to use. Access to this area of the software requires the supervisor password.

Screen Labels

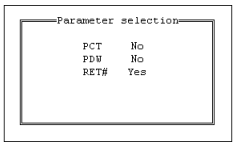
Your laboratory can rename various screen labels to personalize the system and your reports. For instance, if ID#2 is the patient's name, change the label from ID#2 to NAME. New labels appear on the Worklist, Run Samples screen, Data Base Query screen and printouts.

This is also where you set up your primary identifier to be Cass/pos, ID#1, or both.

Note: You must delete the database before changing a primary identifier or any of the screen labels.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Display formats ▸▸ Screen Labels**.
2. Use Spacebar to toggle between Yes and No to select your primary identifier(s).
3. Move the cursor to each label you want to change and type the new label.
4. Press F10 to save and escape.

Parameter Selection

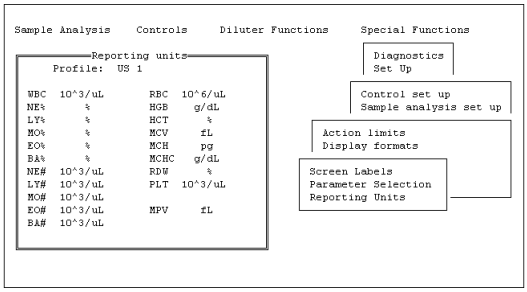


Within the United States and other countries under U.S. FDA jurisdiction, PCT and PDW are for Research Use Only and are Not for Use in Diagnostic Procedures. If you are outside of U.S. FDA jurisdiction and you want to display and report PCT and PDW, set them both to Yes.

If you want to display and report RET# in addition to RET%, set RET# to Yes.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Display formats ▸▸ Parameter Selection**.
2. Move the cursor to the desired parameter.
3. Use the Spacebar to toggle between No and Yes.
4. Press F10 to save and escape.

Reporting Units



Select the Reporting Units you want to use.

Choose between:

- US 1
- US 2 (Retic only)
- SI 1
- SI 2
- SI 3
- SI 4
- SI 5 (Retic only)
- SI 6 (Retic only)
- SI 7 (Retic only)
- JAPA (Japanese)

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Display formats ▸▸ Reporting Units**.
2. Use the Spacebar to toggle to the desired reporting units.
3. Press F10 to save and escape.

Delete database

The patient sample database stores the results of up to 5,000 samples. Sample 5,001 overwrites the oldest sample not marked for saving. Routine deletion of the database is not necessary. Delete the database only in special cases such as changing screen labels. Access to this area of the software requires the supervisor password.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Delete database**.

   The following message appears:
   You have asked to delete the ENTIRE Database. Are you sure you want to delete?: No.
2. Use the Spacebar to toggle to Yes then press Enter.

   This deletes all sample result data and resets the system.

Delete host spooler

Use this feature to clear the buffer of results waiting to be transmitted to the host computer. Access to this area of the software requires the supervisor password.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Delete host spooler**.
2. Press the Spacebar to answer Yes to the displayed question.
3. Press Enter.

Clear printer spooler queue

Use this feature to stop a print job and clear the DMS printer spooler of all data not yet sent to the printer. Access to this area of the software requires the supervisor password.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Clear printer spooler queue**.
2. Move the cursor to the appropriate option.
3. Press the Spacebar to toggle from N to Y.
4. Press F10 .
5. Press the Spacebar to answer Yes to the displayed question.
6. Press Enter.

Print options

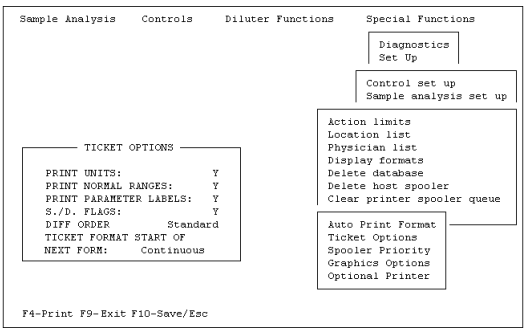
Use print options to set up how you print sample results. Access to some of the options requires the supervisor password.

Auto Print Format

Choose either a graphics format or a ticket format for printouts generated automatically on the printer. Examples of both formats are presented in the Reference manual.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Print options ▸▸ Auto Print Format**.
2. Use the Spacebar to toggle between graphics format and ticket format.
3. Press F10 to save and escape.

Ticket Options



Use to customize the ticket format printout. Choose from these options:

PRINT UNITS Y/N

If Y, the unit strings (such as % and 10^3/µL) print after the data values.

PRINT NORMAL RANGES: Y/N

If Y, the laboratory normal ranges section prints on the report. The ticket report will be 2/3 of a page instead of the normal 1/3 of a page.

PRINT PARAMETER LABELS: Y/N

If Y, parameter labels (WBC, RBC) print along with parameter data.

S./D. FLAGS: Y/N

If Y, suspect and definitive flags print on the report.

DIFF ORDER:

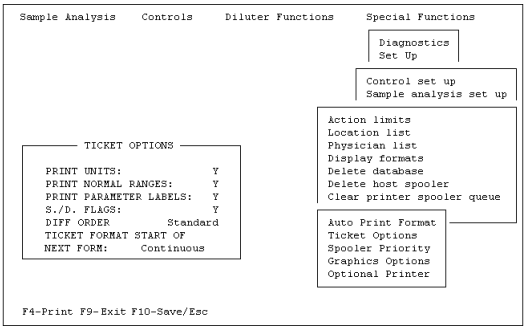
Selects the order that the diff parameters print on the ticket. Options are HmX Standard or STKS (LY prints first).

TICKET FORMAT START OF NEXT FORM:

- If set to Continuous, tickets print with no forms skipped between tickets. The length of the ticket is 1/3 or 2/3 of a form, depending on the setting of the Normal Ranges option.
- If set to Skip One Form, tickets print with one form skipped between tickets depending on the setting of the Normal Ranges option.
- If set to Form Feed, the printer issues a form feed between tickets.

To change an option:

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Print options ▸▸ Ticket Options**.
2. Move the cursor to an option.
3. Use the Spacebar to toggle between Y and N.
4. After you have made your choices, press F10 to save and escape.

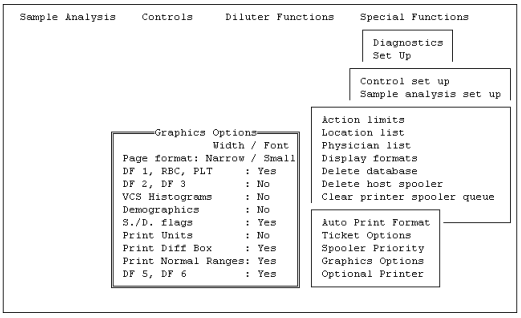


Spooler Priority

If you request multiple print jobs, the printer spooler sends the data to the printer based on the priority you set here.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Print options ▸▸ Spooler Priority**.
2. Use ↑ or ↓ to move the cursor to the item you want to reorder.
3. Press Enter.
4. Use ↑ or ↓ to move the item to its new position.
5. Press Enter.
6. Repeat steps 2 through 5 to reorder other items, if necessary.
7. Press F10 to save and escape.

Graphics Options



Use to customize the graphics format printout. Choose from these options:

Page Format:Width/Font

Use this option to select width (Narrow/Wide) and font (Small/Large).

Wide width = 8.5 in.
Narrow width = 4 in.

- When you select Narrow width, you cannot select Large font.
- If you use Narrow/Small and set all graphics options to Yes, printouts may exceed 11 in. paper.
- DF2, DF3 and VCS Histograms only print when you select Wide width.

DF1, RBC, PLT: Yes/No

If Yes, the DF1 scatterplot, RBC histogram, and Plt histogram print.

DF2, DF3: Yes/No

If Yes, the DF2 and DF3 scatterplots print.

VCS Histograms: Yes/No

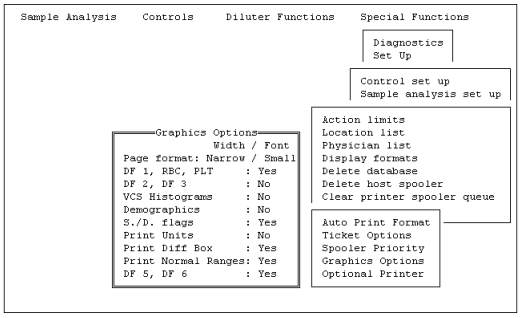
If Yes, the VCS histograms print.

Demographics: Yes/No

If Yes, the patient demographics, including user fields and comments, print.

S/D Flags: Yes/No

If Yes, the suspect and definitive flags print.



Print Units: Yes/No

If Yes, reporting units print.

Print Diff Box: Yes/No

If Yes, the Differential Box prints. This area allows you to handwrite manual diff results on the report.

Print Normal Ranges: Yes/No

If Yes, Laboratory Normal Ranges print.

DF 5, DF 6: Yes/No

If Yes, DF5 and DF6 Retic scatterplots print.

To change an option:

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Print options ▸▸ Graphics Options**.
2. Move the cursor to an option.
3. Use the Spacebar to toggle between settings.
4. After you have made your choices, press F10 to save and escape.

Optional Printer

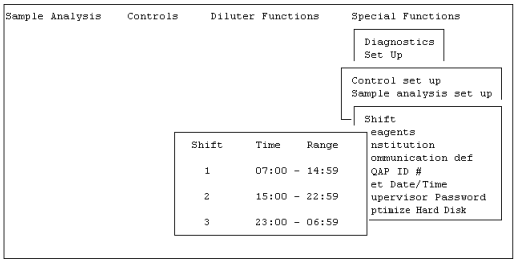
You can add a second printer to your system to print exclusively in ticket format. Connect the second printer to the DMS using LPT2.

1. Select **Special Functions ▸▸ Set Up ▸▸ Sample analysis set up ▸▸ Print options ▸▸ Optional Printer**.
2. Use the Spacebar to toggle between Y and N.
3. Press F10 to save and escape.

6.4 SYSTEM SET UP

Shift

You can use the same bar code-labeled lots of 5C cell control on different shifts and store them in different files. In this way, you can generate separate control statistics for each shift.

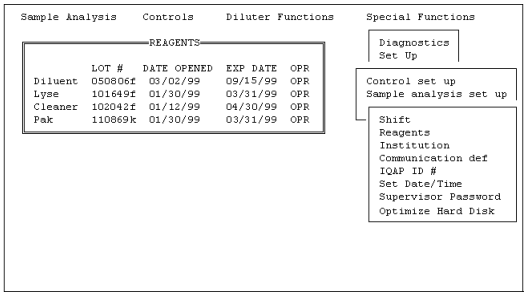


To set this up:

1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Shift**.
2. Type in the starting times for each shift. Press Enter to move the cursor from field to field.
   - The system automatically calculates the end of the shift to prevent overlap.
   - If you only need two shifts, set the third shift to 1 minute. The time periods add up to 24 hours automatically.
3. Press F10 to save and escape.

Reagents

Use this option to record reagent information at installation or whenever you change a reagent. For the complete procedure on how to replace a reagent container, refer to the Special Procedures and Troubleshooting manual, Chapter 4.



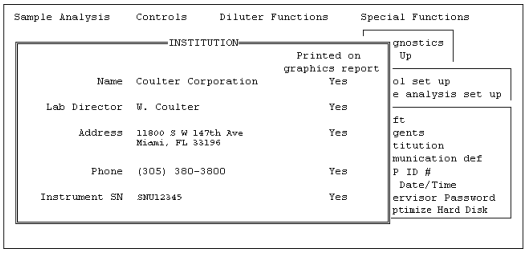
1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Reagents.**
2. Key in the new reagent information, pressing Enter after each item:
   - lot number
   - date reagent opened

     Note: Pressing Enter automatically gives you today's date.
   - expiration date

     Note: Enter revised expiration dates where appropriate, for example, 60 days from date opened for Lyse and Pak, 90 days for Cleaner.
3. Press F10 to save and escape.

Institution

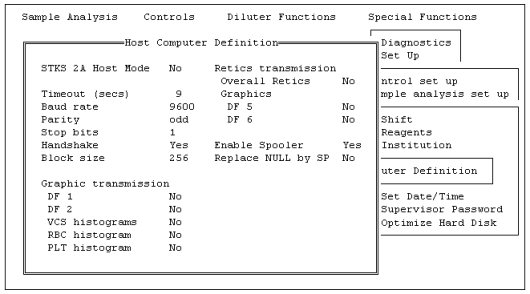
Use this option to determine what institution information prints on the header of your printed reports. Access to this option requires the supervisor password.



1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Institution**.
2. Move the cursor from field to field and type in your institution's information. Use the Spacebar to toggle between Yes and No under the **Printed on graphics report** column.
3. Press F10 to save and escape.

Communication def

Host Computer Definition



Use this option to choose the communication format for transfer of sample information to a host computer. Refer to the Host Specifications manual for information on the transmission of data to a host computer.

1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Communication def ▸▸ Host Computer Definition**.
2. Move the cursor from field to field and type or use the Spacebar to set up each definition.
3. Press F10 to save and escape.

IQAP ID#

Use this option to enter your identification number if you participate in the Interlaboratory Quality Assurance Program (IQAP). This number then appears automatically on all control setup and control review and report displays.

1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ IQAP ID#**.
2. Type your IQAP identification number.
3. Press F10 to save and escape.

Set Date/Time

Use this option to:

- Set the date and time at installation.
- Change the time for a reason such as daylight savings time.

Note: This is not a routine procedure. Date and time continue to update even if you turn off instrument power.

1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Set Date/Time**.
2. Type the date and time using Enter to move from one field to the other.
3. Press F10 to save and escape.

Supervisor Password

Use this option to set up a password to restrict entry into **Sample analysis set up** and parts of **System set up**. Access to this option requires the supervisor password.

1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Supervisor Password**.
2. Type the old password.
3. Type the new password.
4. Press F10 to save and escape.

Optimize Hard Disk

Use this option to enable the OPTune utility so that it automatically optimizes the hard disk when you reset the system. For more information about OPTune, see Optimize the DMS Hard Disk in chapter 4 of the Special Procedures and Troubleshooting manual. Access to this option requires the supervisor password.

1. Select **Special Functions ▸▸ Set Up ▸▸ System set up ▸▸ Optimize Hard Disk**.
2. Verify that Yes is displayed. If it is not, press the Spacebar.
3. Press F10 to save and escape.

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COULTER® HmX Hematology Analyzer with Autoloader Documentation

▪ Reference PN 4237523	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Laser Safety • Reporting Options • Bar-Code Specifications • Sample Tube Sizes • Diff Comparison • References • Glossary • Index
▪ Operator's Guide PN 4237521	System Overview • Startup and Controls • Sample Analysis • Data Review • Shutdown • Set Up • References • Index
▪ Special Procedures and Troubleshooting PN 4237522	Calibration • Reproducibility and Carryover • Cleaning Procedures • Adjust/Replace Procedures • Troubleshooting • Index
▪ Host Specifications PN 4237518	Defines the contents of records transmitted from a HmX Hematology Analyzer to a host computer
▪ Master Index PN 4237525	Combined index for the Operator's Guide, Special Procedures and Troubleshooting, and Reference manuals.

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